Syllabus for ABT 735
Quality Control and Validation

NOTE: This syllabus document contains the basic information of this course. The most current syllabus is available in the full course.

Course Description

Focuses on the importance of quality control and validation in biotechnology product design, development, and biomanufacturing. Explores quality systems and documentation, global quality standards, and methods for assessing validation including installation, operational, and performance qualifications. Overviews biomanufacturing processes, automation, and cGLP/cGMP practices necessary to meet quality standards, focusing on appropriate methods and data analysis, as well as preventive and corrective action.

Prerequisite(s)

ABT 700, ABT 705, ABT 710.

Course Outcomes

Upon completing this course, you will be able to do the following:

- Describe and contrast various quality systems and how Quality by Design is implemented in biotechnology
- Appraise the current quality standards that are used in the US and globally
- Compare the Current Good Practices that are required in biotechnology product development (cGXPs) and assess how they are implemented
- Describe the key aspects of CMC (Chemistry, Manufacturing, and Controls) and how they impact biotechnology product development
- Design a biomanufacturing process including upstream and downstream processes with appropriate in-process and final quality control tests
- Justify the importance of validation (IQ/OQ/PQ) and risk assessment and reduction in biotechnology
- Explain the importance of facilities, equipment, and utilities in biotechnology, and the role of environmental monitoring
- Identify and evaluate current ethical issues in biotechnology related to qualityCourse Requirements/Components

Course Requirements/Components

Exams, Quizzes, Papers & Other Major Graded Work
The summary period will be over the course of the entire semester. Assignments will be included for each week of the course, and vary between individual assignments and group assignments (both oral and written). Assignment will also include discussion postings with required replies to other students in the course.

This course will not involve exams. It will utilize oral and written assignments that more closely match the expectations of the biotechnology industry setting. The assignments will cover the major topics covered in the course and evaluate both depth of knowledge on the topics, but also the appropriate application of the topics to biotechnology. The assignments will require advanced synthesis and demonstrate aptitude and analysis at the graduate level.

Homework & Other Assignments
A supplied grading rubric will be utilized for all assignments. Since a passing grade of C is required for graduate level courses, the grading rubric does not address submitted work that is below this standard except to indicate what unsatisfactory (failing) entails.
All written assignments will be submitted online in Dropbox or Canvas. All oral assignments will be delivered online in the form of narrated PowerPoint presentations, as well as copies submitted online in Dropbox. This is true for both individual and group assignments.

Discussion Postings
Students will participate in one or more online discussion postings per module. Participation is mandatory and will require response to at last one other students. There are graded on a Pass/Fail basis.

Grading

The following grading scale will be used to evaluate all course requirements and to determine your final grade: (examples below)

Grade	Percentage Range
A	94% - 100%
A-	91% - 93%
B+	87% - 90%
B	81% - 86%
B-	78% - 80%
C+	75% - 77%
C	70% - 74%
C-	66% - 69%

F	0 - 65%

Type of Assignment	Frequency	Percentage
Discussion Posts	One or more per module	12%
Individual Written Assignments	Thirteen throughout the course	24%
Individual Oral Presentations	Three throughout the course	12%
Team Written Assignments	Seven throughout the course	34%
Team Oral Presentations	Three throughout the course	18%