Syllabus for ABT 740
Regulatory Practice and Compliance

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

Course Description

Identifies and examines the key regulatory agencies and practices that govern the highly regulated and diverse biotechnology industry, both domestically and internationally. Highlights current and emerging FDA and ICH regulations and guidance documents to successfully navigate meeting with agencies and to submit required documentation for successful product development.

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 the FDA, ICH, EMA, and Japanese PMDA
- Justify the importance of regulatory affairs in biotechnology
- Develop a meeting and communication strategy for interacting with the FDA and submitting appropriate documentation
- Analyze the regulations that impact drug and biologics development, medical devices and diagnostics, agricultural biotechnology, and industrial biotechnology
- Analyze and compare nonclinical and clinical testing and the regulations that govern the use of animals and humans in research
- Describe genome editing and regulatory considerations that impact its applications in agriculture and humans

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. Assignments will also include discussion posts and replies.

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 topic, but also the appropriate application of the topic

to biotechnology. The assignments will require advanced synthesis and demonstrate aptitude and analysis at the graduate level.

Homework and 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.

All assignments will be submitted online in Canvas via the assignment submission option. This is true for both individual and group assignments.

Discussion Sessions
Students will participate in twelve online discussions over the course of the semester. Participation is mandatory both for the initial post and reply.

Grading

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

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%

Assignment	Weight
Individual Oral Presentations	14%
Written Individual Papers	26%
Group/Team Papers	23%
Group/Team Presentations	23%
Discussion Postings	14%
Total Weight	100%