Syllabus for ABT 760
Quality and Project Management

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

Course Description

Quality and project management issues and roles during different phases from R&D to market in the biotechnology industry. Introduction to Installation qualification, operation qualification and process qualification (IQ/OQ/PQ). Project management phases: conceptualizing, planning, executing and closing. Project schedule and time management tools and techniques. Project requirements including quality assurance.

Prerequisite(s)

ABT 720, ABT 725

Course Outcomes

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

- Justify the importance of quality management in biotechnology.
- Analyze the IQ/OQ/PQ validation process.
- Examine the role of quality assurance in product development.
- Examine the design for manufacturing, design for reliability, design for safety and design for sustainability concept.
- Apply the key components of project management.
- Evaluate the relationship of leadership to effective management to maximize outcomes.
- Explain the implementation of ISO and CMMI in biotechnology organizations.
- Use MS Project as a tool to support project management practices.

Course Requirements/Components

Discussion board assignments: 200 pts
You will discuss selected topics from this course with your peers.

Written Assignments: 300 pts
The course features a variety of written assignments that gives you the ability to showcase your grasp of foundational course topics.

Team Presentation: 150 pts

You will as a team to examine the implementation of the Six Sigma and CMMI process improvement in biotech and the use of Quality Audits after implementation of ISO in biotech.

Final Project: 350 pts
You will use SimProject in combination with Microsoft Project to perform a project management case study**.**

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	93% - 100%
A-	90% - 92.9%
B+	86% - 89.9%
B	83% - 85.9%
B-	80% - 82.9%
C+	76% - 79.9%
C	73% - 75.9%
C-	70% - 72.9%
F	0% - 69.9%

Assignment	Points
Lesson 1 Assignment: Written Assignment	50
Lesson 2 Assignment: Written Assignment	50
Lesson 2 Discussion: Quality Programs	50
Lesson 3 Discussion: Sustaining Process Improvement	50
Lesson 3 Discussion: Factors Affecting QM in Biotech	50
Lesson 4 Assignment: Written Assignment 1	50
Lesson 4 Assignment: Written Assignment 2	50
Lesson 4 Assignment: Written Assignment 3	50
Lesson 5 Discussion: Compare and Contrast Quality Management Frameworks	50
Lesson 5 Assignment: Team Presentation	100
Lesson 5 Assignment: Team Presentation Peer Reviews	15
Lesson 5 Assignment: Team Presentation Discussion – Posing Questions	20

Lesson 5 Assignment: Team Presentation Discussion – Responses to Questions	15
Lesson 6 Assignment: Written Assignment	50
Lesson 7 Assignment: Project Charter	50
Lesson 7 Assignment: Root Cause Analysis	50
Lesson 7 Assignment: Process Improvement Plan & Scope Management Plan	50
Lesson 7 Assignment: Statement of Work & Work Breakdown Structure (WBS)	50
Lesson 7 Assignment: Project Management Plan Written Assignment	150
Total	**1000**