REG 6160 – Quality Assurance

Fall 2024

Instructor Information

Course Director

Dawn Lundin, MS

Class Location & Time

Tuesdays 4:00-7:00PM Eastern time, on Zoom

*syllabus is subject to change at professor's discretion

General Information

Description

Quality assurance (QA) plays a critical role in the reliability and reproducibility of product development. As a component of the Quality Management System, quality assurance includes all activities performed by an organization for the prevention of errors and defects. This course intends to focus on QA principles, standards and requirements, with regard to the FDA-regulated product development lifecycle. Further, the course aims to offer examples of QA and quality control measures and oversight through auditing monitoring and risk management as an aspect of inspection readiness. Application of quality assurance and the interfaces between GLP,GCP, GMP-and Pharmacovigilance regulatory regulated activities during clinical development will also be addressed.

Objectives

By the end of this course students will be able to:

1. Evaluate core principles, standards, and methods in the field of quality assurance
2. Define quality control and the relationship to QA
3. Explain root cause analysis (RCA), corrective and preventative actions (CAPA), and communication plan development in overall compliance
4. Evaluate the specific role of QA and risk-based quality management at each stage in the product lifecycle and the interface between development requirements (GLP, GMP, GCP/PV)
5. Identify how QA/QC fits into the QMS as it relates to quality standards and regulations that govern product development and risk-based quality management processes for inspection readiness

Evaluation and Due Dates

Evaluation Methods:
Students will be graded based on class attendance, participation, quizzes and a final exam.

30% – Attendance/Participation
20% - Quality Failure Case Study
10% – Reflections & Discussions
40% – Final Presentation/Case Study

Academic Policies:

Attendance:
Students are expected to attend all classes. If for any reason a student will not be in class, they should contact the Course Director prior to class to alert them of the absence and make arrangements to make up course content. Students are allowed two absences before it may affect their attendance grade.

If a class date conflicts with a holiday or religious observance, please contact the course coordinator. If an assignment is due during this time, please work with the course director and course coordinator to determine an alternative due date.

Academic Integrity:
As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

Course Management: Canvas
All course materials and assignments will be managed on Canvas. Log in with Pennkey and password at https://canvas.upenn.edu.

Course Evaluations:
Course & Lecture evaluations are completed via OASIS throughout the semester. These are a required part of course participation. Students can access evaluation forms with their Pennkey and password and will also receive emails when forms are available: http://gme-evals.med.upenn.edu/

Student Disabilities Services
The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the Office of Student Disabilities Services (SDS). Please make an appointment to meet with me as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235. The office is located in the Weingarten Learning Resources Center at Stouffer Commons 3702 Spruce Street, Suite 300. All services are confidential.

Course Schedule

Date	Topic	Facilitator	Assignment (Due by class meeting)
	Module 1 = Quality Assurance Basics		
8/27	**Introduction to Quality Principles and Standards**	Lundin	
9/3	**ICH E8 (R1)/Elements of Quality Management System Part I Overview**	Asynchronous	ICH and QMS readings Takeaway reflection
9/10	**Main Takeaways from ICH E8 and Elements of Quality**	Lundin	
9/17	**Elements of a Quality Management System Part II**	Asynchronous	Pre-class readings Takeaway reflection
	Module 2 = Quality Assurance in the Product Development Lifecycle		
9/24	**Quality Culture**	Lundin	Pre-class Reading
10/1	**Fall Break**		
10/8	**Quality Failure Project Case Study Topic & Discussion**	Lundin	QFP topic submission & Project Charter
10/15	**ICH E6 R3 Overview**	Tim Stoddard (Proactive Quality Advisor)	Discussion board
10/22	**Introduction to Root Cause Analysis and CAPA Development Methodologies**	Rob Weaver (RW Consulting)/Lundin	Workshop
10/29	**Root Cause Analysis Workshop Continued**	Rob Weaver (RW Consulting)/Lundin	Workshop
11/5	**RBQM Video**	Asynchronous J Rowe	Discussion board
11/12	**RBQM**	Jonathan Rowe (VP ZS) /Lundin	Risk Assessment Workshop
11/19	**QMS Failures**	Sharon Reinhard, President Clinical Compliance Solutions, LLC	Discussion Board
	Module 3 = Quality Assurance Role in Inspections		
11/26	**Monitoring, Auditing, Inspections Video**	Asynchronous	Takeaway reflection
12/10	**BIMO/Mock Inspections**	Lundin/Michelle Weitz (GCP Vision Consulting)	
12/17	**Student Presentations**	Lundin	QFP due

Quality Failure Case Study Presentation:

Select a quality failure or defect from warning letters, personal research experience, or media. The failure can be from any discipline (GLP, GCP, GMP, Safety/PV). If including a personal experience, ensure no identifiers are included (e.g. protocol number, name of lab, staff names, etc.). The selection of failure and possible identifiable causes (steps 1 and 2 below) will be reviewed initially for acceptability and comprise 20% of the grade. The remaining steps will be presented at the end of the course comprising 40% of the grade.

1. Prepare a problem statement that describes the quality failure in detail.
2. Include information and/or data as applicable that supports the possible causes of the problem.
3. Conduct a RCA, including data and methodologies used to support how root cause was analyzed.
4. Develop the appropriate CAPA plan.
5. Include the communication plan to disseminate the problem and CAPA resolutions identified.
6. Develop control measures that will be incorporated to test and confirm quality improvement and sustainability, include any risks that may need to be monitored.