

**MOUNT WACHUSETT COMMUNITY COLLEGE
DEVENS, MASSACHUSETTS**

COURSE OUTLINE

**COURSE: AQS115 Quality Systems and Auditing Principles (3 credits)
 3 credits**

**TEXT: Quality Audits for Improved Performance, 3rd Edition
 Arter, Dennis R
 ASQ Quality Press
 ISBN: 0-87389-570-3**

**SUPPLEMENTAL: ISO 9001:2015 Quality Management System Requirements
 ISO 19011:2011 Guidelines for Auditing Management Systems**

COURSE DESCRIPTION:

This course provides an introduction to various industry (both manufacturing and service) international and US regulatory quality system standards. This course will also provide instruction on the audit process and principles. Prerequisites: ENG098, MAT 096 (or placement); ENG 101 is recommended.

LEARNING OUTCOMES

Students will learn the components of a quality system used in both manufacturing and service industries. The International Organization of Standardization (ISO) library of standards for Quality Systems and Auditing principles will be explored. Students will learn to identify commonality between the standards, along with industry specific differences; demonstrating their knowledge using auditing tools. Students will learn about the formal audit cycle: scope, planning (preparation), execution (performing the audit), reporting and follow-up actions.

OUTCOME ASSESSMENTS:

1. Demonstrate an ability to identify and interpret the ISO standards (e.g. ISO 9001:2015 or ISO 13485:2016) and FDA regulations (e.g. 21CFR 210/211 or 820) used for a variety of manufacturing and service industries, including automotive (TS/ISO 16949), aerospace (AS9001), food manufacture, pharmaceutical, etc.
2. Demonstrate the ability to explain and distinguish different audit types.
3. Demonstrate the ability to differentiate the components of an audit and choose the appropriate tools.
4. Express and practice audit techniques, utilizing graphs and charts to communicate results.
5. Demonstrate the ability to write and speak effectively through written assignments and discussions.

TENTATIVE SCHEDULE OF CLASSES

The instructor reserves the right to make any necessary adjustments to the schedule of topics.

WEEK (date)	LECTURE TOPIC	READING	
		Document	Section
1	Module 1 - Quality Principles Overview	Handout	
2	Module 1 - Organization Roles ISO Standards - overview	Handout	
3	Module 2 - Context of the Organization, Leadership & Planning	ISO 9001:2015	Clauses 4, 5, 6
4	Module 2 - Organizational Supports	ISO 9001:2015	Clause 7
Test #1 (week 5) – Quality Principles & ISO 9001:2015 Clause 4-7			
5	Module 3A - Introduction to Auditing – Types, Terminology, Responsibilities	Arter Text	Chapter 1, 2
		ISO 19011:2011	Clauses 1, 2, 3, 4 5.1, 5.4.1, 5.4.2, 5.4.4, 5.4.5
6	Module 4 - Operations – Planning, R&D, External Provisions	ISO 9001:2015	Clause 8.1 – 8.4
7	Module 4 - Operations – Production/Service, Release & Non-conforming	ISO 9001:2015	Clause 8.5 – 8.7
8	Module 4 - Performance Evaluation & Continuous Improvement	ISO 9001:2015	Clauses 9 - 10
Test #2 (week 9) – ISO 9001:2015 Clause 8-10 & Audit Types			
9	Module 3B - Audit Components – Preparation	Arter Text	Chapter 3
		ISO 19011:2011	Clauses 6.1 -6.3
10	Module 3B - Audit Components – Performance, Tools & Techniques	Arter Text	Chapter 4
		ISO 19011:2011	Clauses 5.4.3 (Annex B); 6.4
11	Module 3B - Audit - Report Out & Follow-up	Arter Text	Chapter 5 & 6
		ISO 19011:2011	Clauses 6.5, 6.6, 6.7
12	Module 3B - Audit – Programs & Training	Arter Text	n/a
		ISO 19011:2011	Clauses 5.2, 5.3, 7
Test #3 (week 34) – Audit Components			
13	Standards Comparison ISO - Medical Device /Automotive / Aerospace US FDA – Medical Device, Pharmaceutical, Bio-Pharmaceutical	Handout	
14	Standards Comparison (cont.) ISO - Medical Device /Automotive / Aerospace US FDA – Medical Device, Pharmaceutical, Bio-Pharmaceutical	Handout	
15	Audit Plan report out / Final Exam		