

AQS 110 FALL 2016 -- Module 1 Study Guide (Exam Review)

This study guide is meant to guide you when in studying for the exam. I hope you find it helpful. It is not a contract of what content will or won't be on the exam. The questions on the exam will be from the topics below.

Textbook – Metrology Handbook

Chapters 2, 3, 4

Module 1 Slide deck Handout

Definition of quality- "...features/characteristics...desirability...controlled to meet....requirements"
Quality determined by end-user

Define Internal versus External customer

Cost of Quality -- know the difference between appraisal, internal, external & preventive

History of Quality: Recognize the philosophy

Frederick Taylor and Scientific Management

Walter Deming – 14 point Quality Management

Joseph Juran – Trilogy

Total Quality Management Principles

Business Process – know how each department is part of the Quality Organization within a Company

Quality Assurance versus Quality Control

Know the difference in responsibility

Recognize the ethics and why an alternate reporting structure

Quality System

Know the Basic premise (5 components)

Understand ISO Voluntary versus FDA Required

Recognize Standard references (ISO9001 vs ISO13485, 21CFR Part 58, 211, 600, 820)

Know the elements (sections) of a quality management system

Know and define acronyms: cGMP, cGLP, cGCP, ISO, FDA, CFR

Identify Good Documentation Practices

Written and electronic