

## Fundamentals of Metrology Topical Content

- I. Introduction & Overview –
  - a. Safety and Orientation
  - b. Course Overview and Introductions
  - c. Good Laboratory Practices (Data Integrity)
- II. Measurement Systems
  - a. Who's Who in the World of Metrology
- III. Traceability (6.5) – GMP 11, GMP 13
  - a. Definitions and Essential Elements – and Risk
    - i. Supplier Evaluation
  - b. Application from Laboratory Measurements
  - c. Tools for assessing the laboratory
- IV. Measurement Exercise (results to be integrated into remaining topics)
  - a. Laboratory "Scope" Addition
  - b. Research: Reviewing Specifications and Customer Requirements
  - c. Inspection of Laboratory Resources: Facility (6.3), Equipment (6.4), Standards (6.5)
  - d. Calibration Items – care, inspection, handling, tracking (7.4), contract review (7.1), sampling (7.3)
  - e. Method Validation (7.2)
  - f. Measurements
- V. Statistics – Foundations for Data Analysis, Measurement Assurance, Method Validation, and Uncertainty Analysis
  - a. Terminology and Concepts
  - b. Measures of Central Tendency and Variation
  - c. Comparative Statistical Tools
  - d. Application from Laboratory Measurements – Team Scenario
- VI. Measurement Assurance (7.7) – GLP 1
  - a. What it is and where it "fits" in the laboratory system
  - b. SOP 30: Check Standards and Control Charts (DMAIC)
  - c. Application from Laboratory Measurements
  - d. Tools for assessing the laboratory
- VII. Uncertainties (7.6) – SOP 29, GLP 9
  - a. Guide to the Expression of Uncertainty in Measurement (GUM)
  - b. SOP 29: 8-step Process
  - c. Rounding Results and Uncertainties
  - d. Application from Laboratory Measurements
- VIII. Proficiency Testing (6.2, 7.7)
  - a. Uses of Interlaboratory Comparisons
  - b. Statistical Tools
  - c. Application from Laboratory Measurements
- IX. Software Verification and Validation (7.11)
  - a. What it is and where it "fits" in the laboratory system
  - b. Tools for assessing the laboratory
- X. Calibration Certificates (7.8)
  - a. Tools for assessing the laboratory
  - b. Application from Laboratory Measurements
- XI. Final Exam

Section numbers are references to ISO/IEC 17025:2017.