

# ISO 17025

## **Purpose**

Employees identify the core elements of ISO 17025 for pharmaceutical and biotech industries.

**Objectives** At the completion of the class, students will be able to:

1. State the historical development of ISO 17025.
2. Explain the requirements of personnel.
3. Explain the requirements for accommodation and environmental conditions.
4. Explain the requirements for test and calibration methods and method validation.
5. Explain the requirements for equipment.
6. Explain the requirements for measurement traceability.
7. Explain the requirements for sampling.
8. Explain the requirements for handling of test and calibration items.
9. Explain the requirements for assuring the quality of test and calibration results.
10. Explain the requirements for reporting the results.

## **Prerequisite**

None

## **About the Class**

1. This class uses group-facilitated discussion, problem solving activities and facilitated instruction to develop a solid understanding of ISO 17025.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 8 hours.

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## Topics Covered

### **1 Scope**

### **2 Normative references**

### **3 Terms and definitions**

### **4 Management requirements**

4.1 Organization

4.2 Management system

### **4.3 Document control**

4.3.1 General

4.3.2 Document approval and issue

4.3.3 Document changes

### **4.4 Review of requests, tenders and contracts**

### **4.5 Subcontracting of tests and calibrations**

### **4.6 Purchasing services and supplies**

### **4.7 Service to the customer**

### **4.8 Complaints.**

### **4.9 Control of nonconforming testing and/or calibration work**

### **4.10 Improvement.**

### **4.11 Corrective action**

4.11.1 General

4.11.2 Cause analysis

4.11.3 Selection and implementation of corrective actions

4.11.4 Monitoring of corrective actions

4.11.5 Additional audits

### **4.12 Preventive action**

### **4.13 Control of records**

4.13.1 General

4.13.2 Technical records

### **4.14 Internal audits**

### **4.15 Management reviews**

### **5 Technical requirements**

#### **5.1 General**

#### **5.2 Personnel**

#### **5.3 Accommodation and environmental conditions**

#### **5.4 Test and calibration methods and method validation**

5.4.1 General

5.4.2 Selection of methods.

5.4.3 Laboratory-developed methods

5.4.4 Non-standard methods.

5.4.5 Validation of methods

5.4.6 Estimation of uncertainty of measurement

5.4.7 Control of data

#### **5.5 Equipment**

#### **5.6 Measurement traceability**

5.6.1 General

5.6.2 Specific requirements

5.6.3 Reference standards and reference materials

#### **5.7 Sampling**

#### **5.8 Handling of test and calibration items**

#### **5.9 Assuring the quality of test and calibration results**

#### **5.10 Reporting the results**

5.10.1 General

5.10.2 Test reports and calibration certificates

5.10.3 Test reports

5.10.4 Calibration certificates

5.10.5 Opinions and interpretations

5.10.6 Testing and calibration results obtained from subcontractors

5.10.7 Electronic transmission of results

5.10.8 Format of reports and certificates.

5.10.9 Amendments to test reports and calibration certificates

### **Summary**

1. Activity: ISO Challenge

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