

Introduction to Laboratory Quality Management Systems

Laboratory Science · Answer Key · 21 Questions

1. What is the definition of 'Quality' according to ISO 9000?

- A) The degree to which a set of inherent characteristics fulfills requirements.**
- B) The accuracy and reliability of test results.
- C) The timeliness of reporting laboratory data.
- D) The efficiency of laboratory processes.

2. Laboratory quality is defined as accuracy, reliability, and what else in reported test results?

- A) Timeliness**
- B) Consistency
- C) Completeness
- D) Accessibility

3. Anecdotal evidence suggests that laboratory results impact up to what percentage of medical decisions?

- A) 70%**
- B) 50%
- C) 90%
- D) 30%

4. Which of the following is NOT a consequence of inaccurate laboratory results?

- A) Unnecessary treatment
- B) Failure to provide proper treatment
- C) Increased patient satisfaction**
- D) Delay in correct diagnosis

5. What is a Quality Management System (QMS) defined as?

- A) Coordinated activities to direct and control an organization with regard to quality.**
- B) The process of examining control materials along with patient samples.
- C) The process by which quality results are ensured by monitoring testing phases.
- D) The system of ensuring laboratory safety and efficiency.

6. Quality Assurance (QA) is a process that ensures quality results by monitoring which phases of testing?

- A) Preanalytical, analytical, and postanalytical**
- B) Pre-examination, examination, and post-examination
- C) Collection, testing, and reporting
- D) Sample receipt, analysis, and storage

7. Quality Control (QC) involves examining control materials to monitor which aspects of the analytical process?

- A) Accuracy and precision**
- B) Reliability and consistency
- C) Timeliness and completeness
- D) Validity and integrity

8. In a QMS, what aspects of laboratory operation need to be addressed to assure quality?

- A) Organizational structure, processes, and procedures**
- B) Only analytical processes and equipment
- C) Customer service and reporting
- D) Personnel training and safety protocols

9. Which of the following is NOT listed as a Quality System Essential?

- A) Equipment
- B) Customer Feedback**
- C) Process Improvement
- D) Information Management

10. Walter A. Shewhart is credited with the development of what in the 1920s?

- A) Statistical Process Control**
- B) Continual Improvement
- C) Quality Trilogy
- D) Four Absolutes of Quality

11. W. Edwards Deming is known for his contribution to which quality concept?

- A) Continual Improvement (PDCA/PDSA cycle)**
- B) Statistical Process Control
- C) Quality Trilogy
- D) Micro-scale Error Reduction

12. Joseph M. Juran is associated with the 'Quality Trilogy', which includes QP, QC, and what?

- A) QI (Quality Improvement)**
- B) QA (Quality Assurance)
- C) QR (Quality Review)
- D) QS (Quality Standards)

13. Philip B. Crosby is known for the 'Four Absolutes of Quality', which includes prevention over appraisal and what else?

A) Conformance to Requirements and Zero Defects

- B) Continuous Improvement and Cost of Quality
- C) Customer Focus and Teamwork
- D) Process Control and Documentation

14. ISO 9001 is a standard for what?

A) Quality Management System Requirements

- B) Quality management in the clinical laboratory
- C) General requirements for the competence of testing laboratories
- D) General requirements for proficiency testing providers

15. ISO 15189 specifically addresses quality management in which setting?

A) The clinical laboratory

- B) Manufacturing industries
- C) Testing and calibration laboratories
- D) Proficiency testing providers

16. CLSI stands for:

A) Clinical and Laboratory Standards Institute

- B) Council for Laboratory Science and Innovation
- C) Center for Laboratory Standards and Information
- D) Committee for Laboratory Scientific Advancement

17. What is the primary purpose of sample management in a laboratory?

A) To ensure the accuracy and reliability of testing.

- B) To reduce the cost of laboratory operations.
- C) To speed up the reporting of test results.
- D) To minimize personnel effort in sample handling.

18. Which of the following is an example of a potential error during sample collection?

A) Incorrect patient identification

- B) Proper transport conditions
- C) Adequate specimen volume
- D) Correct collection time

19. Consequences of collection errors can include delays in reporting, unnecessary re-tests, and what else?

A) Incorrect diagnosis/treatment

- B) Increased customer satisfaction
- C) Reduced costs
- D) Improved patient outcomes

20. What is the role of the Laboratory Handbook (SOPs) in sample management?

A) To provide standardized procedures for sample handling.

- B) To record patient demographic information.
- C) To track the cost of reagents.
- D) To communicate with external laboratories.

21. Essential information on a test requisition typically includes:

A) Patient identification, tests requested, and time/date of collection.

- B) Collector's personal contact information.
- C) The laboratory's financial account number.
- D) Detailed patient medical history.