Quality Management System Model

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OBJECTIVES

- Implementation of a Quality Management (QM) program
- To describe the twelve (12) quality system essentials
- To explain types of documents utilized in QMS
- To describe the ethical practices in QMS

Implementation of a Quality Management System

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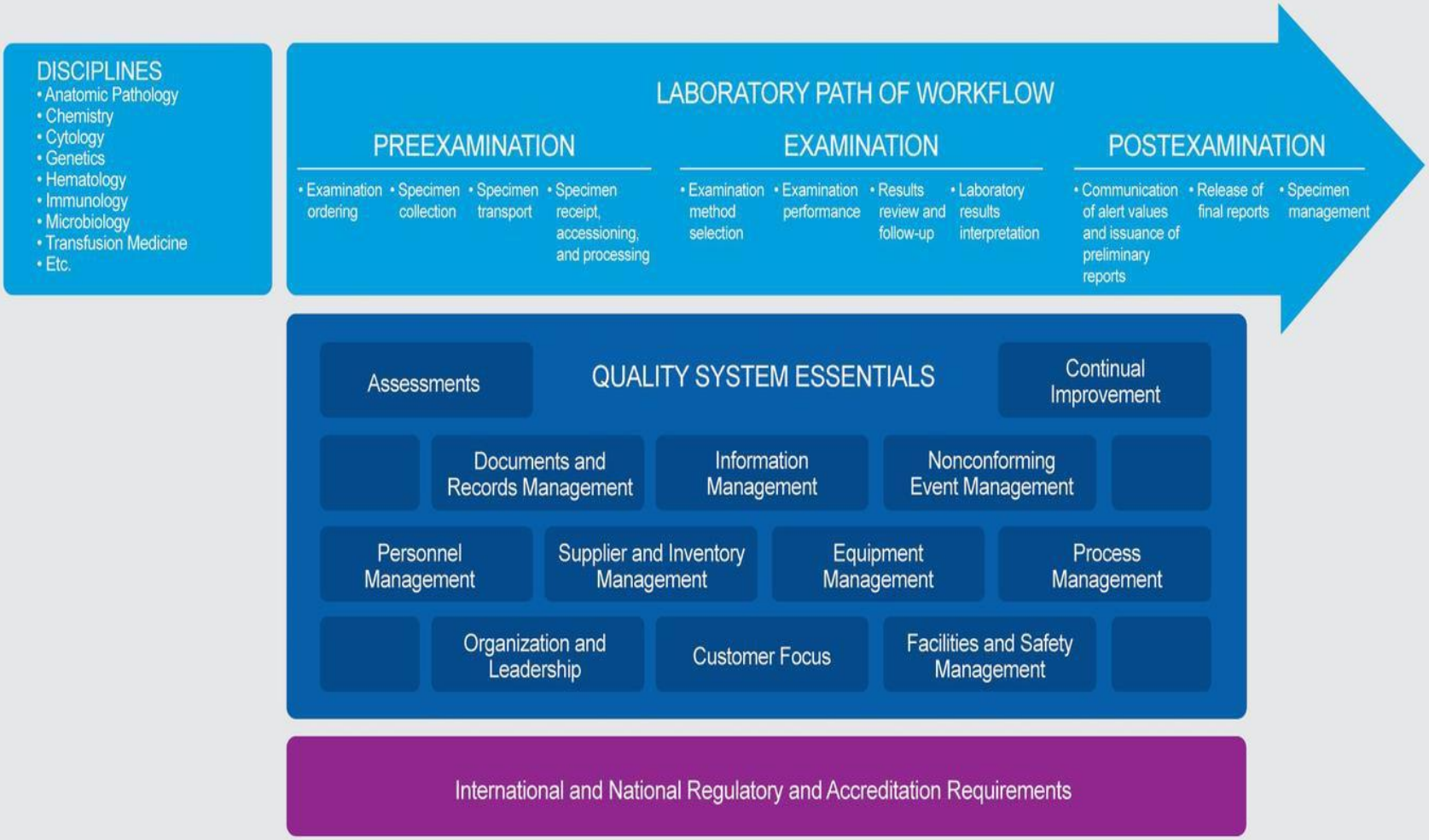
QMS system model for laboratory service



Source: CLSI

GCP COMPLIANCE AND QUALITY MANAGEMENT

GCP COMPLIANCE AND QUALITY MANAGEMENT

The laboratory must have a written quality management (QM) program to systematically ensure the quality of laboratory services.

- Policy for communication of employee concerns
- Sampling of quality indicators with follow-up actions when targets are not achieved
- Annual appraisal of effectiveness of the QM Program
- Document control policy
- Record/specimen retention policy
- Error, complaint, and incident logs with corrective/preventative actions
- Device-related adverse patient event procedure and records of reporting (ifapplicable)
- Results of the laboratory's self-inspection and correction of deficiencies
- Sampling of records of manufacturer's recalls and records of follow-up

Twelve (12) Essential Elements of Quality Systems

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Quality System Essentials

The Clinical Laboratory Standards Institute (CLSI) defines twelve (12) Quality system essentials (QSE) are the building blocks of a total quality management system (TQMS):

1. Organization
2. Customer focus
3. Facility and Safety
4. Personnel
5. Purchasing and Inventory
6. Equipment
7. Process Management
8. Documents and Records
9. Information Management
10. Nonconforming Event Management
11. Assessment
12. Continual Improvement

Quality system essentials

The twelve (12) can be further categorized by impacted laboratory examination phase:

- ✓ Pre-examination/Pre-analysis phase
- ✓ Examination/analysis phase
- ✓ Post-examination/post-analysis phase of laboratory path of workflow

Quality System Essentials

1. Organization

Organizational structure should be defined to Describe leadership responsibilities that are integral to a laboratory's success in achieving and maintaining a systematic approach to quality and meeting regulatory, accreditation, customer, and internal requirements.

Quality System Essentials

Well defined organizational structure ensures:

- A top-down commitment to quality (e.g., Implementation of a Quality Policy and Quality manual)
- Roles and responsibilities of line management and personnel are clearly defined
- QMS is effectively implemented and maintained, and exhibits continuous quality improvement
- Proactive planning of resource requirements to include: facility, personnel, capital and material resources
- Development and definition of quality goals and utilization of tools for tracking achievements (e.g., use of quality metrics)
- Requires routine quality reports for management review
- Defines requirements for routine communications to internal and external stakeholders/customers to ensure QMS driven activities and issues are readily communicated

Organizational structure to Support Quality Management Systems (QMS)

Quality Manual development and implementation is an essential element of a functional QMS and the principal elements for a successful quality management system are

- Top-Down Managerial commitment to quality
- Top-Down Managerial commitment to ***sufficient resources*** to ensure implementation and on-going support
- Organizational structure must be developed to ensure that quality goals of the organization are defined, implemented and met and that the organization remains committed to defined quality goals ensuring a state of continuous quality assurance
- Implementation must be monitored by defining *Key Indicators (e.g., monitoring turn-around-times)* related to critical customer/patient outcomes

2. Customer focus

The laboratory customers/patients are at highest risk for negative impact related to poorly implemented QMS, therefore, the laboratory must ensure customer satisfaction by:

- By clearly identifying the customer/patient and their expectations, and the need to design efficient work-flow to meet expectations.
- By ensuring the customer/patient can provide the laboratory with feedback by implementation of methods to seek customer/patient input to conform that expectations are met and that the laboratory can identify opportunities for improvement.

3. Facility and Safety

- The laboratory should plan and implement process to ensure the laboratory environment is both ergonomically designed and safe for laboratory personnel, i.e., physical environment, maintenance and safety programs should be clearly defined.

Quality System Essentials

Facilities and Safety concerns should include (but not be limited to) the following:

- Allocate appropriate space for laboratory activities
- Ensure limited access to the laboratory for only authorized personnel.
- Maintain cleanliness and monitor the environment
- Provide safety protocols and training to include the following topics :
  - Biosafety and blood borne pathogens
  - Occupational health, accidents and illness
  - Fire protection
  - Chemical hygiene
  - Hazardous waste management
  - Business continuity and Emergency management

4. Personnel

- All laboratory personnel regardless of their function must be trained and qualified with respect to their charge and such training ***must be documented***.
- Laboratory requirements must be defined to ensure an appropriate number of qualified and competent laboratory staff are recruited and retained.

Note: Personnel are the most important laboratory resource.

Quality system essentials

Effective management of laboratory personnel includes:

- Development of job descriptions to clearly define personnel qualifications and responsibilities.
- Development of proper on-boarding training to Introduce new staff to the organization and laboratory
- Implement effective initial and continuous training programs (Personnel should be trained and assess upon hiring; at 6 months from hiring and annually thereafter)
- Reviews of staff performance and routinely assess competence
- Provide for and encourage continuing education and professional development
- Development, maintenance and storage of personnel files

5. Vendors, Purchasing and Inventory

- The laboratory must implement procedures to identify, qualify and manage laboratory vendors and suppliers
- Critical vendors and suppliers should be qualified by audit prior to use to ensure efficient and cost- effective operations and to identify potential risks to availability of reagents, supplies and services.

Quality system essentials

The following should be considered when evaluating vendors:

- **The quality department should qualify laboratory vendors, suppliers, contractors and consultants *PRIOR TO USE***
- **Once qualified vendors/suppliers should be subject to on-going performance review**
- **Once consumables are delivered to the laboratory the laboratory is responsible for:**
  - Inspection and verification of received materials.
  - Storage and handling of devices and materials per manufacturer's specification
  - Management of inventories of reagents and materials

Quality System Essentials

Laboratory should establish Purchasing and Inventory management program to ensure

Supplies and rea gents are always available

Quality is maintained

Minimized wastage
Stay within the budget

6. Equipment

- Implement process for selection and installation of equipment, equipment maintenance and calibration,
- Documentation of equipment related problems and record maintenance to ensure that equipment performs as expected for intended use.
- Ensure proper management of the equipment in the laboratory to ensure accurate, reliable, and timely testing/analysis.

Quality System Essentials

Laboratory equipment must be subject to the following controls:

- Select, qualify and acquire needed laboratory equipment and instruments by vendor qualification.
- Define equipment calibration and maintenance procedures to ensure:
  - Laboratory devices are subject to installation, operational and performance qualifications, Calibrate measuring equipment per manufacturer's schedule
  - Maintain equipment and instruments per manufacturer's requirements as defined by the User's Manual
  - Decommission equipment no longer in use
  - Document all equipment maintenance and calibration activities

Note: if a laboratory device is moved/relocated it must be subject to reinstallion and calibration as applicable

Quality system essentials

Develop a maintenance plan and document all related activities

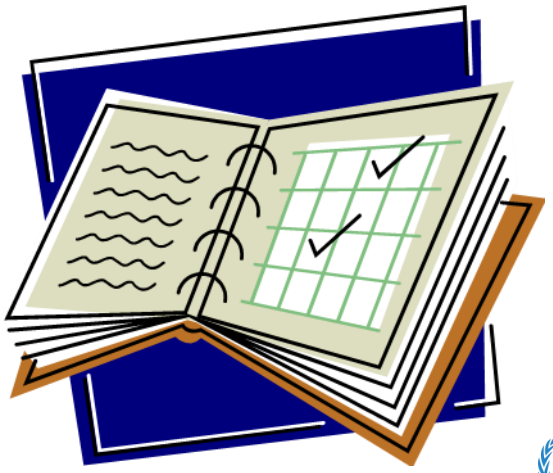
- **Routine Maintenance and preventive :** Develop and document a detailed schedule of routine maintenance according to manufacturers instruction.
- **Scheduled Maintenance:** includes service repair by manufacturer, calibration, function check plus any other problems
- **Occurrence Logs** details of all problems encountered, and steps taken to rectify the incident, i.e., Corrective and/or Preventive Actions must be documented

Quality System Essentials

Equipment inventory log must be created to define the following:

- ✓ Instrument type, model number, serial number (unique identifier)
- ✓ Location in laboratory
- ✓ Date purchased
- ✓ Manufacturer and vendor contact information
- ✓ Warranty, note expiration date

Equipment identification	
Equipment type	
Trade mark	
Type	
Serial#	
Register record#	
Date first use	
Reseller	
Buying type (new, reconditioned, used)	
Equipment performance	
Specific items when using the equipment	



7. Process management

- ✓ Describes processes directly and indirectly related to the laboratory's path of workflow to optimize both effectiveness and cost
- ✓ Process should be continually evaluated to ensure customer expectations, and regulatory/accreditation requirements are met

Quality System Essentials

Examples of process management are:

- Design, document and review the laboratory's path of workflow and quality system essentials
- Validate and verify that processes are effective
- Develop and implement control plans (e.g., Quality plans for analysis/examination methods)
- Develop and implement process for managing changes (i.e., change control procedure)

8. Documents and records

Describes the creation, management and retention of the policy, process and procedure documents for the quality system essentials and path of workflow

9. Information Management

- Provide guidance for managing the information generated and entered into a *paper based or electronic record* keeping system
- The laboratory needs to limit access to its record management systems by:
  - Ensuring interfacing control (e.g., pertaining to electronic hospital/laboratory information systems that systems are independent and only accessible via a secure interface)
  - Cleaning and maintenance staff
  - Unauthorized offsite laboratory staff

Quality System Essentials

Basic requirements related to Information Management

- ✓ Planning for information needs
- ✓ Maintaining confidentiality of information
- ✓ Security for data access
- ✓ Integrity of data transfers or transmissions
- ✓ Provision of information availability during downtime

Quality System Essentials

Electronic Systems (e.g., LIMS) and Security :

- All electronic systems and software utilized in support of all or part of the three (03) phases of laboratory analysis must be ***validated prior to use and remain in a state of continuous validation***.
- Identify who may perform specific functions in the system
- Establish appropriate security levels of computer access for each job title or individual user
- Establishing password configuration and frequency of change
- Change Control process must be established (e.g., to support changes to system security and/or configuration)
- Modifying software datafiles
- Amending verified results or interpretations, or adding addendums

10. Nonconforming event Management

The laboratory must define and implement processes to support:

- ✓ Detection and documentation of nonconformances,
- ✓ Manage products and services that do not meet specified requirements,
- ✓ Classifying nonconformances for analysis, and a process for corrective and/or preventive measures.

Quality System Essentials

Nonconforming event management should include requirements for

- ✓ Documentation and reporting of events
- ✓ Investigation of events, to include root cause analysis and corrective/preventive actions.
- ✓ Respond to external recalls and defective materials (e.g., US FDA requirements for medical device reporting)
- ✓ Routine review of quality trends (e.g., use of levey-Jennings plots)

11. Assessment

The laboratory must implement a process to conduct routine and thorough interim self-inspections/audits and document any corrective/preventive measures implemented to address deficiencies

- Describes the use of external and internal monitoring and assessments to verify that laboratory processes meet requirements and to determine how well those processed are functioning
- Ensure written evidence (e.g., audit reports) of self-inspection findings with records of corrective/preventive actions

Quality System Essentials

Additional quality assessment to include proficiency testing (PT), QC sample exchange:

- Participation in PT programs for all examination methods
- Alternative assessment of examination methods when formal PT is not available
- Quality indicators for process measurements

12. Continual Improvement

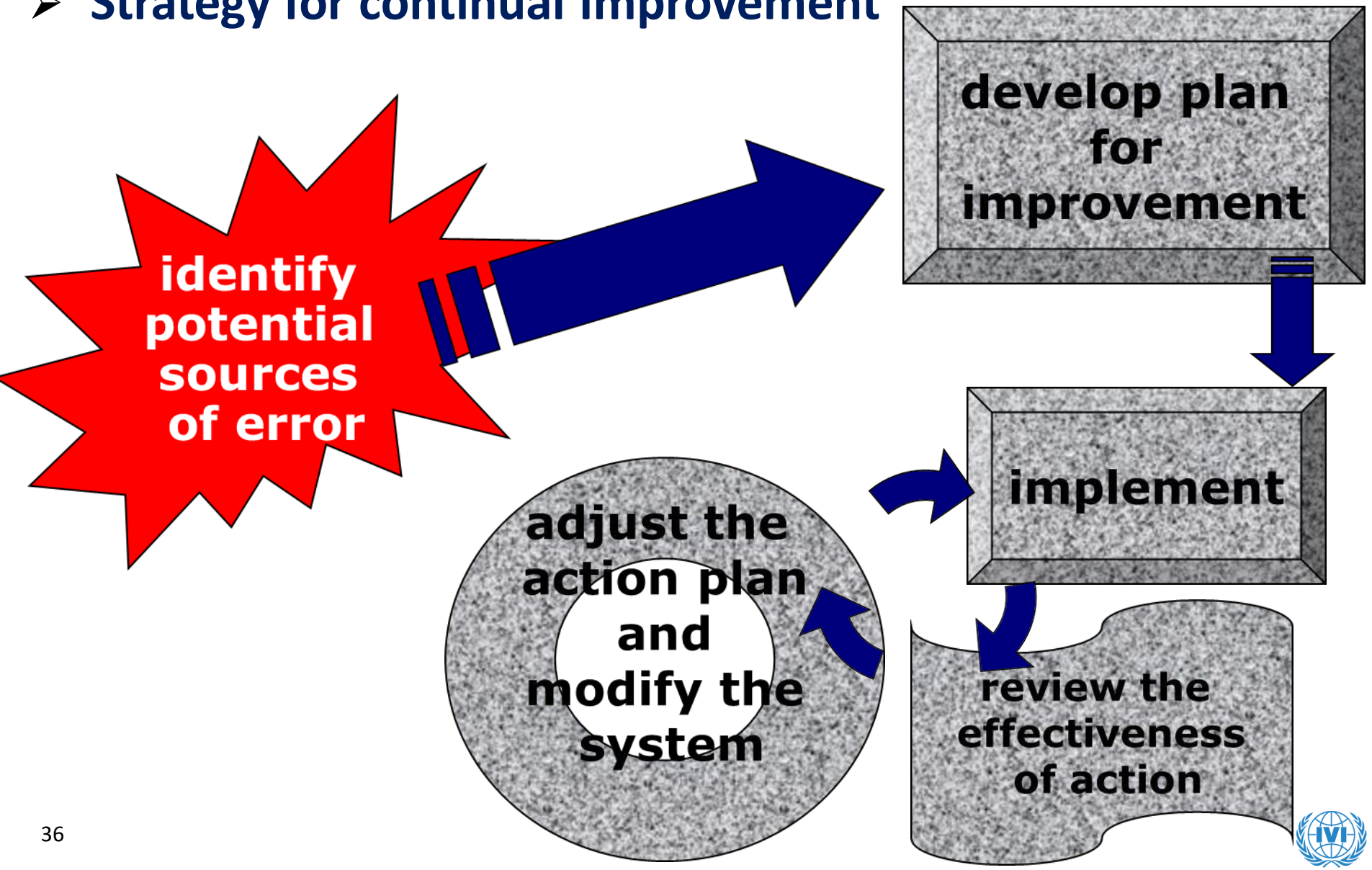
Continual improvement is the core of quality management and requires:

- Organizational and management commitment to quality
- Effective Planning,
- Infrastructure development,
- Dedicated leadership,
- Oganization wide participation,
- Sustained engagement.

Continual improvement is an outcome of an active and dedicated **laboratory** quality management system.

Quality System Essentials

- **Strategy for continual Improvement**



SUMMARY

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Quality System Essentials

An effective compliance program is ensured by:

- Standards and Procedures
- Oversight Responsibility
- Education and Training
- Lines of communication
- Auditing
- Monitoring
- Enforcement and Discipline
- Response and Prevention

LABORATORY ETHICS

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Ethical Practice in QMS

Ethical Considerations in the Laboratory

Uphold standards of professionalism, be honest in all professional endeavours, and maintain a high level of personal integrity. ISO15189

Ethical Practice in QMS

- 1. Uphold standards of professionalism, be honest in all professional endeavours, and maintain a high level of personal integrity.
- 2. Avoid scientific and professional misconduct including, but not limited to fraud, fabrication, plagiarism, concealment, inappropriate omission of information, and making false or deceptive statements.
- 3. Report any health care professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel.

Ethical Practice in QMS

- 4. Maintain a high level of quality in the product(s) of professional endeavours, including validity and reliability of test results, interpretive opinions, publications, and scientific research.
- 5. Respect the privacy and confidentiality of protected health information encountered during the course of my professional activities in accordance with legal and ethical obligations.
- 6. Continuously strive to augment the professional qualifications, knowledge, and skills, and present them accurately.

Ethical Practice in QMS

- 7. Promote the safety and welfare of patients, employees, coworkers, colleagues, the public, and the environment.
- 8. Avoid, or promptly disclose and work to resolve, actual or potential conflicts of interest.
- 9. Encourage open and honest discussion among physicians, other healthcare providers and/or facility managers regarding disclosure to patients of information about medical errors, if such information is material to any patient's well-being.
- 10.Comply with relevant laws and seek to change them when they are contrary to the best interests of the patient."

Ethical Practice in QMS

- All personnel involved in the laboratory's QMS share a responsibility to ensure that ethical practices are followed

- Laboratory management and staff should be free from any undue internal and external commercial, financial, or other pressures and influences that could adversely affect the quality of their work.

SUMMARY

- Implementation of a Quality Management (QM) program
- To describe the twelve (12) quality system essentials
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QUESTIONS

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Questions and Answers

1. **You are the Laboratory Manager in a Medical Research Centre. The Chemistry instrument laser/filter required replacement. The manufacturers Technical Representative/Engineer was informed of the issue and visited the lap to repair the malfunctioning Chemistry instrument. The Tech Representative was in a hurry and had to depart the lab for his return flight. He did not have time to provide documentation supporting the equipment repair and instructed laboratory personnel that he would send the paperwork to the lab when he reached his office. The Lab staff on the late shift reported to work after the Technical Representative/Engineer had left and the lab staff immediately processed 13 samples that were stored in the refrigerator 2 -8 C. The Lab Tech analyzed the samples and reported and released the results to the Clinician on call. The Clinician on call noticed an elevated ALT, AST, and gamma GT on 3 different patient results. The Clinician called the Lab to confirm the 3 results since they were not correlating with the patient's conditions.**

- **What factors could have contributed to this scenario?**
- **How will you investigate this occurrence?**
- **Should the Doctor trust the other 10 results?**
- **As the Laboratory Manager, what measures will you put in place to prevent this from recurring?**

Answer

1. **What factors could have contributed to this scenario?**

a. The analyzer part was replaced but calibration was not done
b. Personnel issue (e.g., lack of training)
c. Staffing/workload
d. Staff handover
e. Incomplete equipment service

2. Should the Doctor trust the other 10 results?

a. The doctor should not make any decision on the 13 results until the root cause is investigated and resolved

3. **How will you investigate this occurrence?**

a. Run QC materials
b. Check calibration
c. Repeat the 13 samples (old samples and fresh samples)

Answer

4. **As the Laboratory Manager, what measures will you put in place to prevent this from recurring?**

a. Use the incident as an opportunity for improvement
b. Arrange for staff training
c. Clarify the contract with the vendor and spell out the scope of work
d. Standard operating procedure
e. Equipment logbook
f. Staff handing over a log

References

- International Organization for Standardization. ISO 17025:2017 General requirements for the competence of testing and calibration laboratories. http://imed.ir/userfiles/files/11/ISO-IEC%2017025-2017.pdf
- International Organization for Standardization. ISO15189 : 2012 Requirements for quality and competence https://www.iso.org/standard/56115.htm
- Laboratory Quality Management System (LQMS) training toolkit https://www.who.int/ihr/training/laboratory_quality/introduction/en/
- CLSI. Quality management system: A model for laboratory services; approved guidelines https://clsi.org/standards/products/quality-management-systems/documents/qms01/

Quality Management System Essentials