Introduction to Laboratory Quality Management Systems (QMS)

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Objectives

- **Review History and purpose of Quality Management (QM)**
- **Understand Quality Management, Compliance and Shared Obligations**
- **Identify applicable laboratory regulations/accreditations requiring QM implementation**
- **Understand the three (03) Phases of Laboratory Analysis and Impact to Quality**
- **Understand organizational structure to support Quality Management Systems (QMS)**

HISTORY

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A Brief History of Quality Management

General Concepts of Quality Management are well established and apply to multiple industries

Innovator	Date	Cycle
Walter A.Shewhart	**1920s**	Statistical Process Control
W. Edwards Deming	**1940s**	Continual Improvement
Joseph M. Juran	**1950s**	Quality Toolbox
Philip B. Crosby	**1970s**	Quality by Requirement
Robert W. Galvin	**1980s**	Micro Scale Error Reduction

A Brief History of Quality Management

WALTER A. SHEWHART

The father of statistical Quality who successfully brought together the disciplines of statistics, engineering, and economics and became known as the father of modern quality control.

https://asq.org/about-asq/honorary-members/shewhart

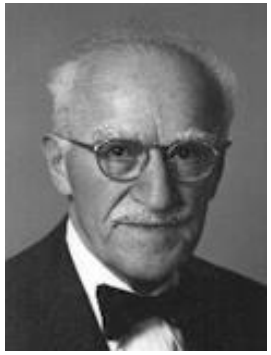
A Brief History of Quality Management

W. EDWARDS DEMING

Recognized for his role as adviser, consultant, author, and teacher to some of the most influential businessmen, corporations, and scientific pioneers of quality control, is the most widely known proponent of statistical quality control. He has been described as a national folk hero in Japan, where he was influential in the spectacular rise of Japanese industry after World War II; as a curmudgeon; as the high prophet of quality control; as an imperious old man; and as founder of the third wave of the Industrial Revolution.

https://asq.org/about-asq/honorary-members/deming

A Brief History of Quality Management



JOSEPH M. JURAN

*"It is most important that **top management** be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below."*
— Joseph M. Juran

Juran emphasized the need for top management involvement, the Pareto principle, the need for widespread training in quality, the definition of quality as fitness for use, the project-by-project approach to quality improvement. These are the ideas for which Juran was best known, and they are still widely used today.

https://asq.org/about-asq/honorary-members/juran

A Brief History of Quality Management

PHILIP CROSBY

The Guru of Quality Management

Philip B. Crosby was a legend in the discipline of quality. A noted quality professional, consultant, and author, he is widely recognized for promoting the concept of "zero defects" and for defining quality as conformance to requirements.

https://asq.org/about-asq/honorary-members/crosby

A Brief History of Quality Management

Robert W. Galvin

The 'inventor' of the Six Sigma process which is a method that provides organizations tools to improve the capability of their business processes. Defined by an increase in performance and decrease in process variation helps lead to defect reduction and improvement in profits, employee morale, and quality of products or services.

https://asq.org/quality-resources/six-sigma

A Brief History of Quality Management

History of Laboratory Regulations and Standards to Include Quality Requirements:

- **Clinical Laboratory Improvements Act (CLIA)** - implemented in USA in 1967 in response to poor quality of laboratory reports which arose in the cytology laboratories that read PAP smears. In 1967, the Clinical Laboratory Improvement Amendment was passed and the first laboratory regulations were born.
- **College of American Pathologists (CAP)** – international clinical/medical accreditation program. First CAP lab accreditation was in the USA in 1964
- I**SO15189** – Developed with support from CAP and initiated in 2003 supporting clinical/medical labs and accreditation
- **ISO17025** – non-clinical/medical biological laboratory standards defining basic laboratory systems that can be applied broadly to various laboratory disciplines. Established 1999

COMPLIANCE AND QUALITY MANAGEMENT

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COMPLIANCE AND QUALITY MANAGEMENT

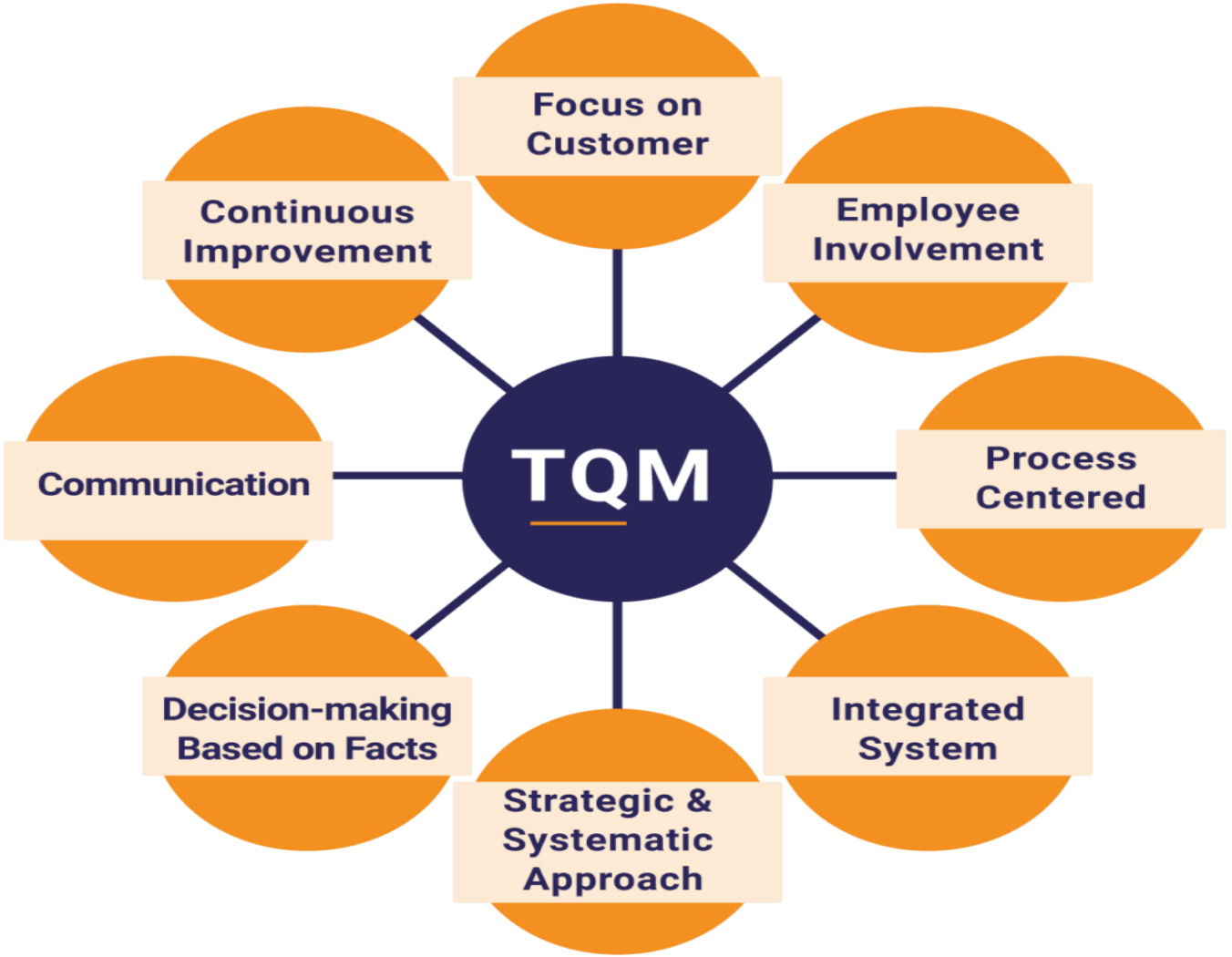
COMPLIANCE AND QUALITY MANAGEMENT

- Total Quality management (TQM) includes the design of efficient monitoring tools and procedures for data collection and processing, as well as the collection of information that is essential to decision making, which ensures laboratory reporting is **accurate, reliable, and timely.**

- Compliance with the laboratory quality and accreditation standards (e.g., ISO17025, ISO15189, CLSI and WHO) ensures ***accuracy, reliability, and timeliness of the reported test results and ensures the safety of patients is protected.***

Note: This also relates to laboratories involved with the humane treatment of animal populations, as applicable.

GCP COMPLIANCE AND QUALITY MANAGEMENT



Quality Assurance (QA) and Quality Control (QC):

GCP COMPLIANCE AND QUALITY MANAGEMENT

Compliance is ensured through implementation of established laboratory standards, defined process (e.g., SOPs) and regulatory and accrediting organization requirements to include (but not limited to) the following:

- **ISO17025:2017 General requirements for the competence of testing and calibration laboratories**
- **ISO 15189:2012 Medical laboratories — Requirements for quality and competence**
- **Clinical Laboratory Standards Institute (CLSI) – Global Laboratory Standards**
- **(WHO) Laboratory Quality Management System (based on ISO15189 and CLSI)**
- **Country specific regulatory requirements (e.g., US CLIA 42CFR493)**
- **Laboratory Standard Operating Procedures**

GCP COMPLIANCE AND QUALITY MANAGEMENT

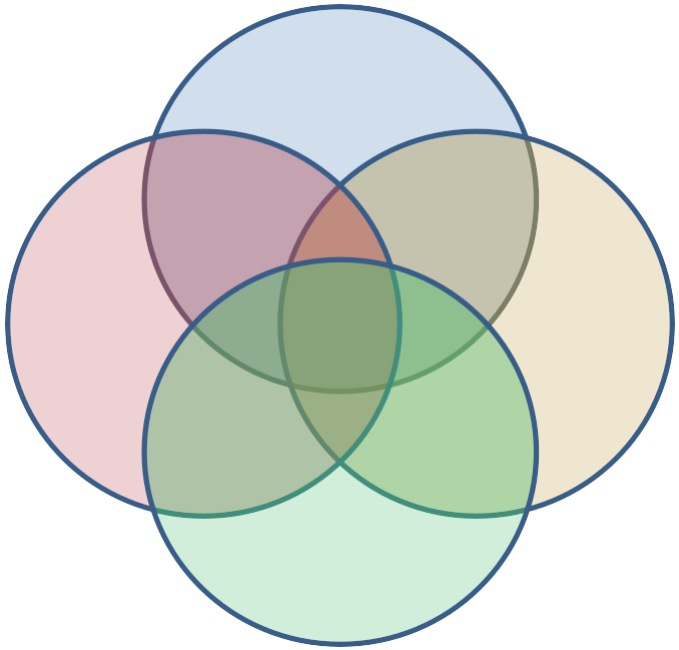
Compliance is ensured through implementation of established laboratory standards, defined process (e.g., SOPs) and regulatory and accrediting organization requirements to include (but not limited to) the following:

LABORATORY DISCIPLINE	LABORATORY CATEGORY	APPLICABLE INDUSTRY STANDARD OR GUIDANCE
Clinical/Medical Laboratory	Clinical/Medical Laboratory	•CLIA – 42 CFR 493 (US Mandated) •CAP •ISO15189
Bioanalytical (non-human)	Non-clinical/medical Laboratory	•21 CFR 58 – Good Laboratory Practice for Nonclinical Laboratory Studies •OECD – Principles of Good Laboratory Practice and Compliance Monitoring
Bioanalytical (Human)	Non-clinical/medical Laboratory	•No codified regulatory requirement exists to describe bioanalytical analysis of ***human samples***; however, Good Clinical Laboratory Practice (GCLP) guidance is utilized by select government organizations, e.g., WHO, US NIH, etc.)

QMS is supported by a System of Mutual Accountability

Regulatory Authorities and Accrediting Bodies

Laboratory Management



Laboratory Quality Oversight

Customers/Patients

QMS is supported by a System of Mutual Accountability

Ensuring Laboratory Compliance to Regulations and Standards is a shared responsibility by:

- Regulators and Accrediting bodies, Lab Management and Quality Oversight
- Responsibilities overlap – system of checks and balances
- Each party is independently responsible for compliance with ***Laboratory Executive Management holding ultimate responsibility for implementation of quality management systems***
- Failure in any of the shared responsibilities will impact customer confidence and patient safety

PHASES OF LABORATORY ANALYSIS

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Three (03) Phases of Laboratory Analysis and Impact to Quality

Source WHO

Three (03) Phases of Laboratory Analysis and Impact to Quality

The Path of Workflow of any laboratory (e.g., clinical/medical, bioanalytical, etc.) is divided into three (03) phases of analysis:

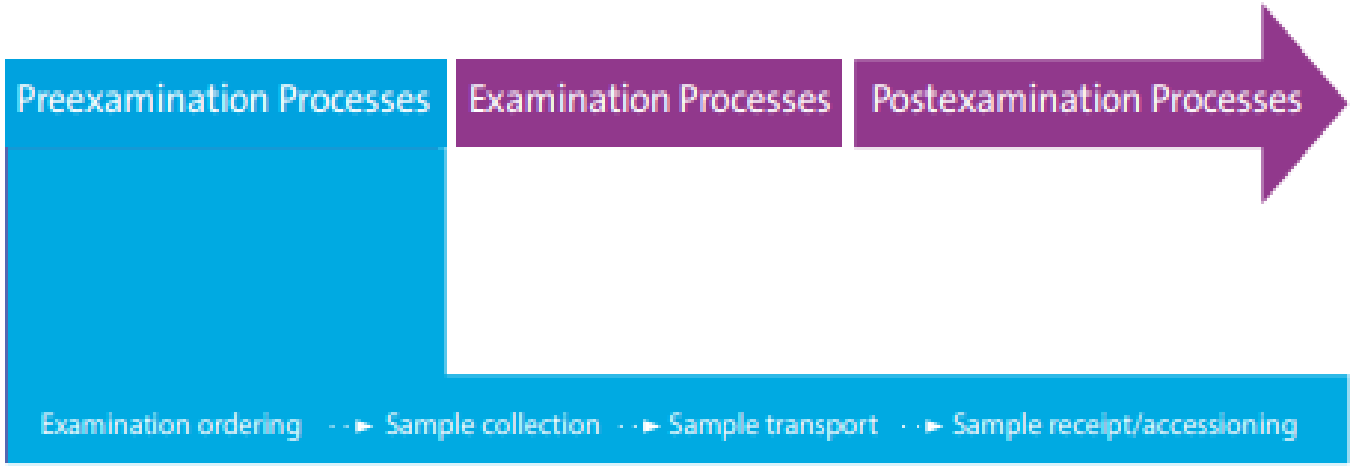
- Pre-analytical/Pre-examination phase
- Analytical/Examination phase
- Post-analytical/Post-examination phase

Note: A failure of any one of these critical phases of clinical laboratory testing can significantly affect the integrity of a laboratory result.

Three (03) Phases of Laboratory Analysis and Impact to Quality

Pre-analytical/Pre-examination phase

Represents all variables that can impact sample integrity *prior* to the analysis/examination phase.

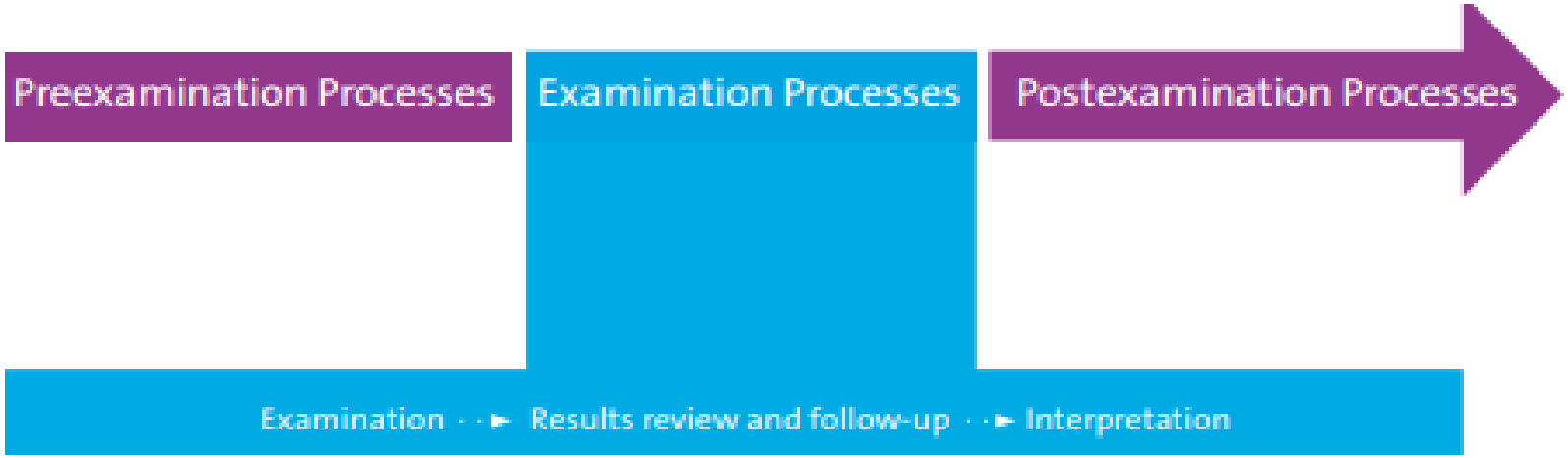


Source CLSI

Three (03) Phases of Laboratory Analysis and Impact to Quality

Analytical/examination phase

Represents all variables that can impact sample integrity and analysis *during* the testing phase.

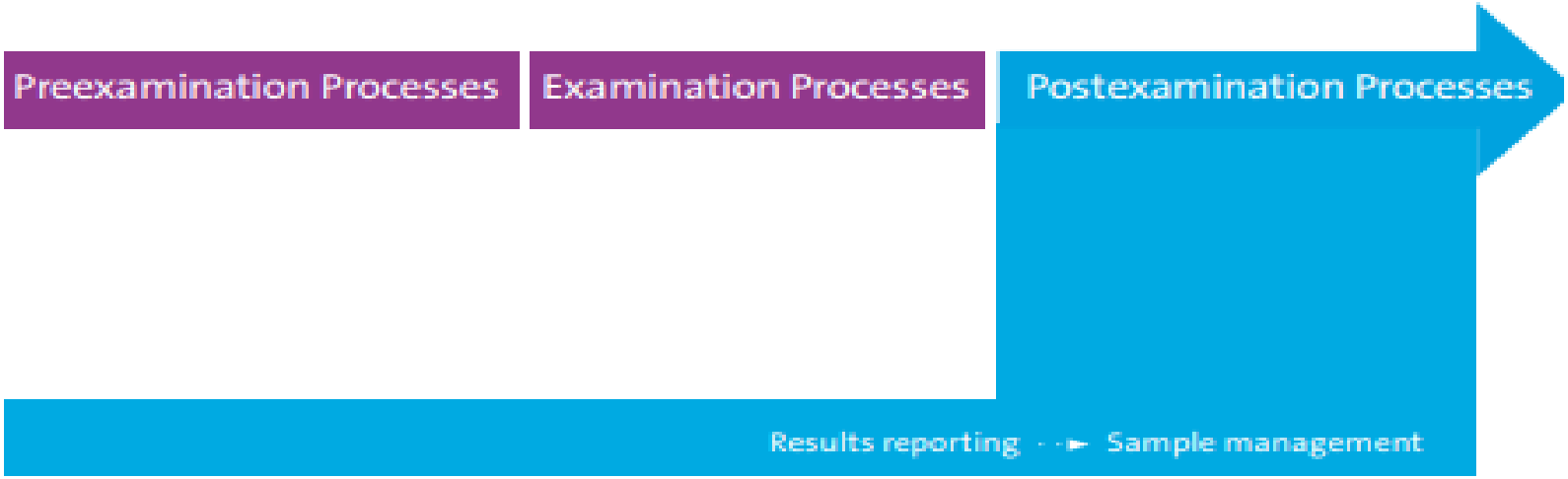


Source CLSI

Three (03) Phases of Laboratory Analysis and Impact to Quality

Post-analytical/post-examination phase

Represents all variables that can impact result reporting and follow-up.



Source CLSI

Three (03) Phases of Laboratory Analysis and Impact to Quality

CLINICAL LABORATORY ANALYSIS PHASE	VARIABLES IMPACTING PHASES OF ANALYSIS (i.e., Key Indicators)
Pre-analytical/Pre-examination phase	• Specimen transport and environmental control of shipping containers • Specimen requisition and accessioning • Analytical method and electronic system validation • Phlebotomy and sample collection methods • Sample storage • Interfering substances
Analytical and Examination phase	• Preparation of slides, solutions, calibrators, controls, proficiency testing materials, reagents, stains, quality of water and other materials used in testing • Definition of reportable ranges for test results (i.e., normal values) • References to manufacturer's test system instructions, package inserts and operator manuals • Identification of panic or alert values (as applicable)
Post-analytical and Post-examination phase	• Report formatting (i.e., electronic or paper formats which are associated with unique patient identifiers, laboratory identifiers, identification of test reference intervals and normal ranges) • Review, approval and release of result reports and corrected reports • Verification of accurate and timely final report receipt • Post-analysis sample storage and result retention.

LABORATORY ORGANIZATIONAL STRUCTURE

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Organizational structure to Support Quality Management Systems (QMS)

Organizational infrastructure 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 provide ***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

Organizational structure to Support QMS

Executive management must ensure acquisition of an experienced quality professional to support initial infrastructure development and define short and long-term organizational and departmental goals.

The following are examples of quality management responsibilities:

- ✓ Monitor quality management system
- ✓ Ensure compliance
- ✓ Review critical laboratory documentation
- ✓ Conduct and coordinate audits (e.g., internal audits and vendor qualifications)
- ✓ Investigate deficiencies and manage corrective and preventive measures (CAPA)
- ✓ Inform decision makers

Organizational structure to Support QMS

Ensure that QMS oversight is established as an objective process without undue influence by the functional areas that are overseen by quality, i.e., the organizational structure must be ***objective and independent*** *to ensure:*

- The Quality Assurance (QA) Department is established with direct line of reporting to executive Management
- **QA Management must report** to the highest-level executive in the organization, such as the **laboratory** business unit **head** in a hospital or the **CEO** of an organization.

Note: QA should not report to the Laboratory Director as this a conflict of interest. QA should have authority by virtue of direct line management to the head of the organization.

Organizational structure to Support QMS

QMS implementation and development process:

- Define a Quality Policy which should be approved by executive management
- Develop and Implement a Quality Manual to describe the basic tenants of the quality management system to include (but not limited to):
  - ✓ Lines of communication between functional areas,
  - ✓ Framework for meeting expectations related to Quality Manual defined system requirements and
  - ✓ Demonstration and definition of the organizations executive management commitment to quality assurance and supporting quality operations and quality systems.

Organizational structure to Support QMS

QMS implementation and development process (cont):

- Ensure that quality oversight is established as an objective process without undue influence by the functional areas that are overseen
- Implement and continuously improve the quality system (i.e., continuous quality improvement)
- Establish *quality systems* to manage and support controlled document development and implementation (e.g., Policies, manuals, SOPs, WI, etc.)
- Partner with the organization and provide leadership and mentoring
  - ✓ Exercising responsible authority, while providing motivation and vision.
  - ✓ Build the team that is cohesive.
  - ✓ Influencing and encouraging staff to good performance

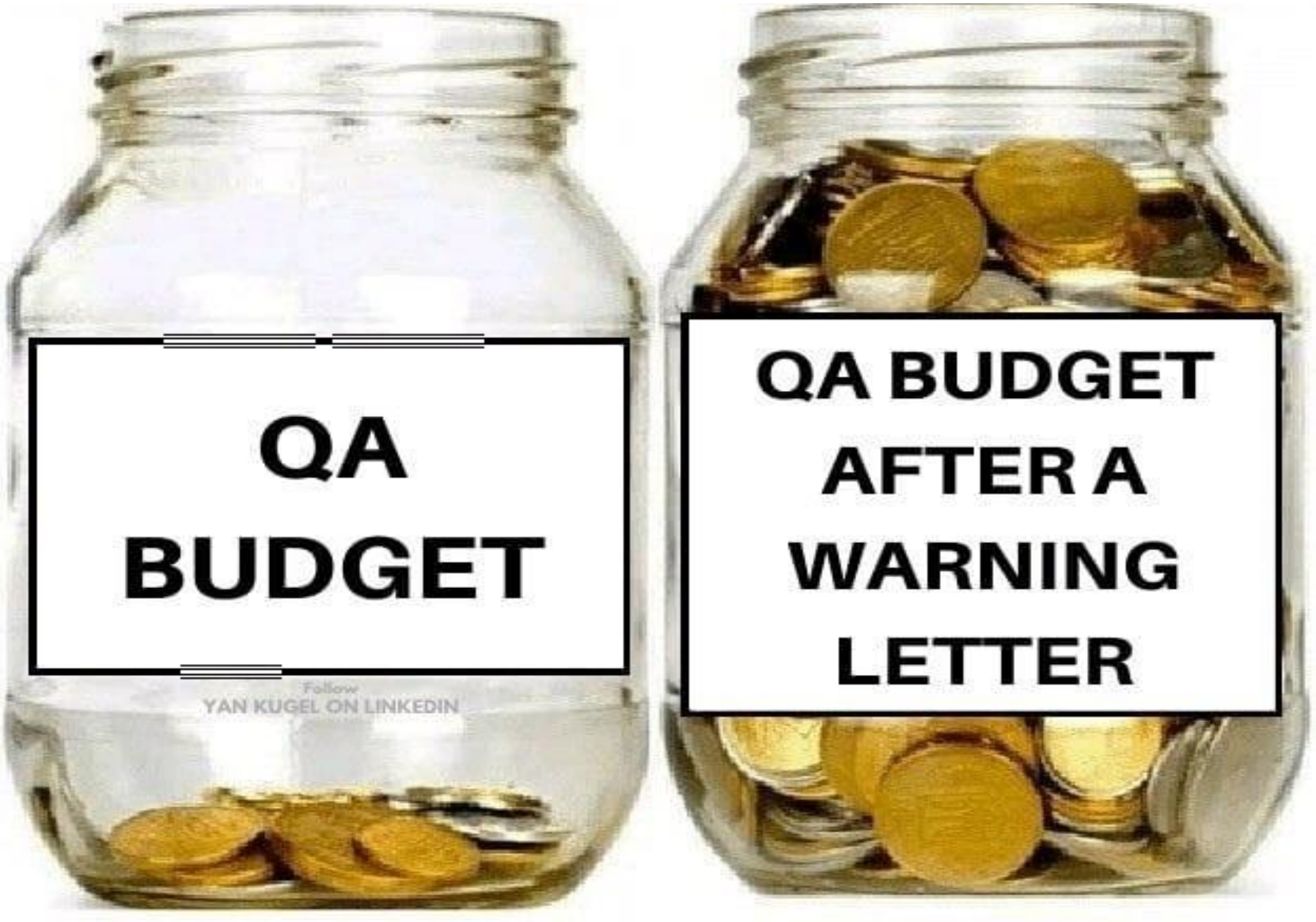
Note: Never enforce quality efforts by use of punitive actions as this will serve only to demotivate and will negatively impact the QMS implementation and sustainability

Organizational structure to Support QMS

QMS must be adequately resourced and sufficient resources identified through frequent assessment of quality infrastructure through:

- ✓ Identification of financial requirements/budget planning
- ✓ Review Personnel needs:
  - Staffing requirements
  - Skills and training opportunities for personnel
- ✓ Facilities, equipment, supplies, computers

QMS BUDGET


QA
BUDGET
Follow
YAN KUGEL ON LINKEDIN
QA BUDGET
AFTER A
WARNING
LETTER

SUMMARY

Successful implementation of a quality management system requires planning, management commitment, an understanding of the benefits, engaging staff at all levels, setting realistic time frames, and looking for ways to continually improve.

QUESTIONS

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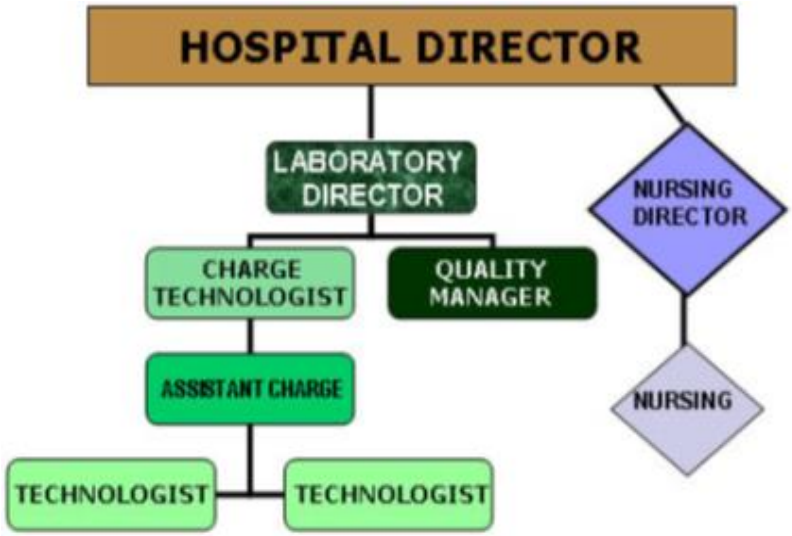
CASE STUDY

If you are designated as a quality assurance manager in a peripheral hospital laboratory and if there is no quality management system in place, what steps do you follow to implement QMS?

Answer

1. Obtain top-down commitment from executive management (e.g., hospital director).
2. Develop organizational chart defining line of authority and responsibility (e.g.)



3. Perform a gap analysis using a checklist to evaluate the laboratory practice

Answer

4. Develop a work plan defining a task list of everything needs to be addressed e.g.

List of tasks	Responsibility	Timeline	Remark
Quality manual was not available	Quality manager	One month	
Quality police was not developed	Laboratory director	Two weeks	
Document control system was not available	Quality manager /assigned personnel	Two weeks	
Develop polices and procedure	All staff	6 month	

5. Form a team to develop quality management processes and procedures

6. Develop a quality policy

7. Develop quality manual and define content and objective

8. Develop of processes for controlling documents and records

Answer

9. Develop a program for nonconforming event management
10. Customer service and satisfaction program
11. Facilities and safety plans
12. Personnel programs
13. Purchasing and inventory programs
14. Equipment management plans.
15. Analysis and verification of QSE and path of workflow processes with the development of procedures or instructions
16. Information management program
17. Continual improvement program

Answer

18. Monitor the effectiveness of the quality management system:

- Management review
- Internal audit
- Develop Quality indicators (IQC, stock out, equipment downtime, EQA, external audit..)

References

- College of American Pathologists (CAP) - Laboratory General Checklists Edition 06/17/2010 (www.CAP.org) , Global search for CAP accredited Laboratories / CAP History Timeline
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- 21 CFR 58 – Good Laboratory Practice for Nonclinical Laboratory Studies http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=21:1.0.1.1.22&idno=21
- OCED – Principles of Good Laboratory Practice and Compliance Monitoring http://www.oecd.org/officialdocuments/displaydocumentpdf/
- 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/


Thank You
Gracias!
Merci!
Danke Schoen
ありがとう
THANKS
謝謝
спасибо
Tak!
شكرا
GRAZIE
Merci!
salamat
Thanks
gracias
감사합니다
謝謝