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**" IMPLEMENTING LABORATORY QUALITYMANAGEMENT  
STANDARDS TO IMPROVE CLINICAL DIAGNOSTIC  
SERVICES IN PORTSAID GOVERNMENTAL HOSPITALS "**

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## **ABSTRACT**

LQMS helps laboratories to enhance internal laboratory processes, attain workers and client satisfaction. undefeated achieving of (LQMS) could be an obligatory demand to pass national and international accreditation. during this study, analysis of (QSI) in 2 major laboratories generally hospitals in Port-said governorate in Arabic Republic of Egypt, covering all system necessities were administrated. The study analysis was administrated by rating the degree of achievement of (QS's) parts in several executive activities of laboratory system. knowledge was collected by checking the labs' processes against the World Health Organization check list's demand. This study, emphasize that safety coaching is a necessary component, and might function as a significant role in making sensibility and connotation to achieve (QS) in sanitary experimenting lab. Therefore, ought to be time coaching within portions of lab. activities specially safety. Project conclude that safety defects were the main challenge in sanitary experimenting labs interpret necessity for the concept of safety national and international customary necessities of (QS) achievement, maintaining for enhancing (Q) actions of labs and assess accreditation. Ignore the achievement of (QS) will give rise a drop in services and therefore accreditation opportunity.

Key words: (LQMS), laboratory safety, achievement, coaching.

### Introduction

(LQ) are often outlined as precision, responsibility and time achieving of reportable check outcomes. lab outcomes should be correct, all aspects of lab. operations should be trusted, and time saving coverage for helpful during a clinical or public health setting.[1]

Passive sequels of lab. mistakes

Labs give check outcomes which are wide utilized in secret and general health settings, and patient treatment outcomes believe the reliable of the experimenting processes and coverage mechanisms. If unreliable outcomes submitted, the implications are often terribly vital, including:

- Unnecessary treatment or generally operations
- Treatment complications
- Medications side effects
- Missing necessary diagnoses
- Failure to produce the right treatment
- Increased price of aid.

These consequences end in inflated cost, time and employees' endeavors, and sometimes in poor patient outcomes.

### Minimizing lab mistakes

To realize the very best level of precision and responsibility, it's necessary for whole processes and procedures within lab. To be done at absolute excellent approach. The lab. is a complicated system, including several steps of activity and plenty of folks. The (QS) needs a lot of processes to be done. So, (QSM)model, that appear at the whole system, is extremely necessary to achieve smart lab. functioning. [2]

### Definition of quality management system

(QMS) may be outlined as "arranged actions to steer and management a company with regarding to goodness".

This definition is employed by (ISO) and by (CLSI).

In (QMS), every side of the lab. practicability, as well as the framework and methods, aim to confirm quality. [1]

The quality of the lab. system needs these several agents should to confirm goodness within the lab. a number of these agents are:

- the ambience of lab.
- quality control
- connections
- conservation of registry
- clever employees
- goodness of reagents and instrumentation.

Components of the standard management system model

Quality management has been around for regarding 800 years. The ideas initial utilized in medieval European guilds are coagulated and refined over the centuries into what's currently referred to as quality management systems. the quality management system (QMS) model has been custom-made to the medical laboratory setting leading to a dozen necessities that type the framework for quality. The model for the subsequent twelve necessities is from (CLSI) and ISO 15189. [3]

**Obtaining an effective (LQMS), the management structure of the lab. should be described and ordered properly. Laboratory leadership will be responsible to establish and develop effective policies and procedures for all technical and administrative activities. Finally, evaluation and monitoring must be part of the organization structure of the laboratory to ensure effective implementation of the system components.**

## **1. Personnel**

Competent, qualified, and motivated workforce is one of the quality system pillars. Starting by staff credentialing, assignment, and orientation and ending with staff firing or ending contracts, all should be clarified and documented as an important function of the quality systems.

## **2. Equipment**

Laboratory critical and non-critical equipment management is side of the (QMS) to confirm its proper selection, installment, validation, calibration, proper functions, and having a system for emergency and periodic preventive maintenance.

## **3. Purchasing and inventory**

The purchase and stocking of reagents and provisions in the lab. is a defying mission. Administration of purchase and stocking reduce the price and confirm that provisions and reagents are obtainable when necessary.

## **4. Process control**

Many agents are necessary to confirm the goodness of lab. methods which may involve quality control for testing, administration of the sample, and method verification and validation.

## **5. Information management**

Laboratory and patient data need to be collected, analyzed, and presented properly to take accurate decisions. Moreover, maintaining data and information confidentiality and integrity is really a challenge in the new developments of the information technology and must be incorporated in the (LQMS).

## **6. Documents and records**

Many instruments are needed or generated from the laboratory technical and administrative processes. Examples could include but not limited to policies, procedures, plans, programs, quality control results, patient results, incident reports, regular audits and checks, financial statements and registries. That's why document management system is a crucial component of the quality management system of the laboratories.

## **7. Occurrence management**

An “occurrence” is associate degree surprising event that ought to not have happened. A proactive or reactive system is required to observe and report these issues or incidents, to manage properly, and to forestall its repetition.

### 8. Assessment

The assessment and audits a method by that the laboratory leadership will check the lab. execution and examination, it to the quality, execution of alike lab. Estimating could also be inner (by same lab. employees) or outer ( a personnel or agencies out of the lab.).

### 9. Process improvement

Continuous quality improvement of the laboratory processes is one amongst the objectives of the implementation of the quality system in laboratories. There are variety of tools that are helpful for method improvement (like, six sigma, PDCA, and brain storming).

### 10. Customer service

The idea of client service has typically been unnoticed in lab. apply. so, it's vital to notice that the laboratory is a corporation providing each a service and a product; thus, it's essential to see customers of the laboratory, what they have, and the way a lot of they're satisfies concerning the services or merchandise provided.

### 11. Institutions and safeness

These agents involve:

- Security—which is the method of stopping undesirable dangers from coming into the lab. area.
- Inclusion—which attenuate dangers from going away the lab. area and inflicting hurt to the society.

- Safeness—which involve policies and procedures to forestall hurt to staff, guests and therefore the society.
- Ergonomics—which direct facility and instrumentality modification to permit secure and hygienic operating status at the lab. web site

### Aim of the work

The parsing of the study was applied by evaluation the implementation of (QSI) in numerous activities of lab. framework in 2 main hospitals in Port-said governorate. Information gained from checking the labs by making check list to aim of (QMSI).

Objective of the study was to:

- Allow compared functioning and outcomes between completely differ check locations
- Offer advanced precautions to systematically issues related to kites or transactions.
- Provide proof of (Q) of experiments.
- Indicate zones require to be better.
- Identify coaching requirements

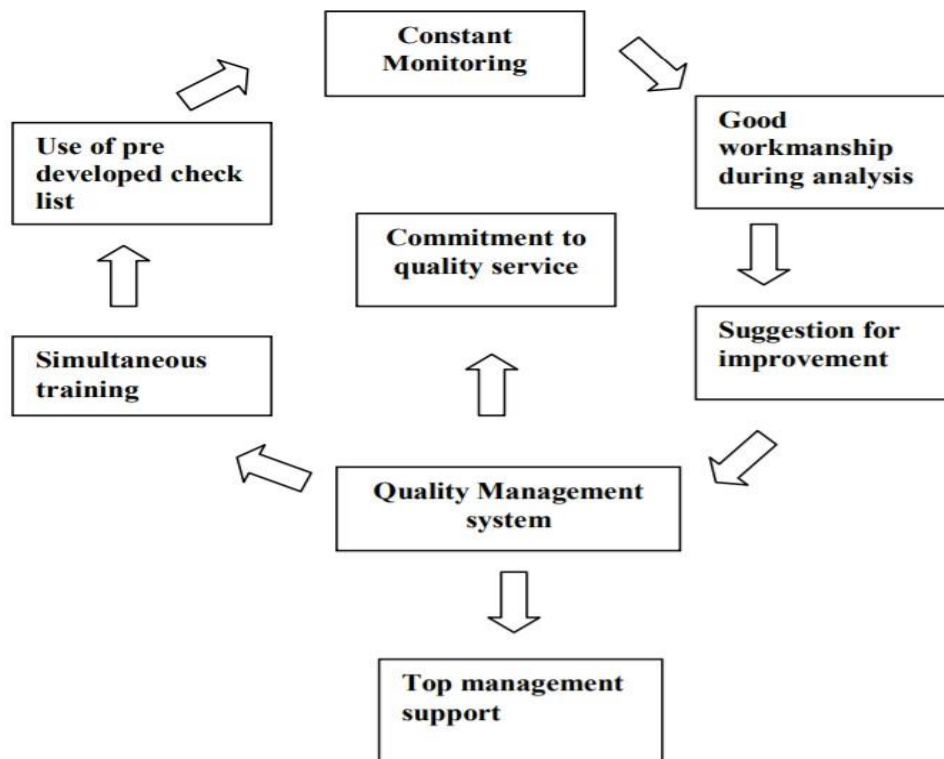
Labs are basic post within sanitary (QS). Results of experiments are a necessary and keeping living inside sanitary caring regulation and trust correct and dependable check outcomes. So, (Q) confirmed checking of ill people specimens is significant (WHO, 2006). (LQI) is in a very higher situation to fulfill the wants of (IS). Accreditation is best once it's stock-still in a policy context for assessment (LQ) and ill people safeness (Trevor et al., 2010) [4]. It can make clients trusted in whole sections. moreover, it can increase sanitary experimenting to international agreeable, comparative tier. [5]

(LQMS) didn't take its whole interest within the zones of sanitary experimenting lab. actions. By the recent amended standard by -BSI (2012) each lab. ought to have (QS) to administer whole functional and administration method and therefore the method flow of (QMS) as seen in Figure1.

(QSI) within the lab. not solely gives certifying however conjointly credibleness to efficiency in labs. Accreditation method can make sure the quality of the

take a look at results and successively confirms(Q). Current study taken to pursue achievement of ongoing regulative adherence associated with (QS) in sanitary experimenting labs. Study parsing was made to spot optimize and conserve (QSI). The measures to optimize, attain present demand of (QS) within experimental labs mentioned.

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**Figure 1.** Process flow of quality management system.

## Methodology

Studying was carried out in 2 major sanitary experimental labs in Port-said governorate in Egypt. These labs study parsing within the regard of (QSI) in keeping with (WHO) measures. This regardation is native. Actual time study parsing was carried out like (WHO) scores supported the check list was made. Study choice study parsing made on (QSI), and its connection to up the (Q) of sanitary experiments in labs. Studying examine requirements to achieve (QS) by individuals for defined actions. This enclosed eligible, coached lab. head,



(Q) administrator, functional administrator, top lab tech in studying. It was achieved in each lab. with register departments on doc and registers, regulation and individuals, instruments, getting and stocktaking, method management inner/outer quality survey and utility and integrity. Our study was distributed to analyze achieving of (QS) and its continuity as per World Health Organization standards.

## Discussion and Results

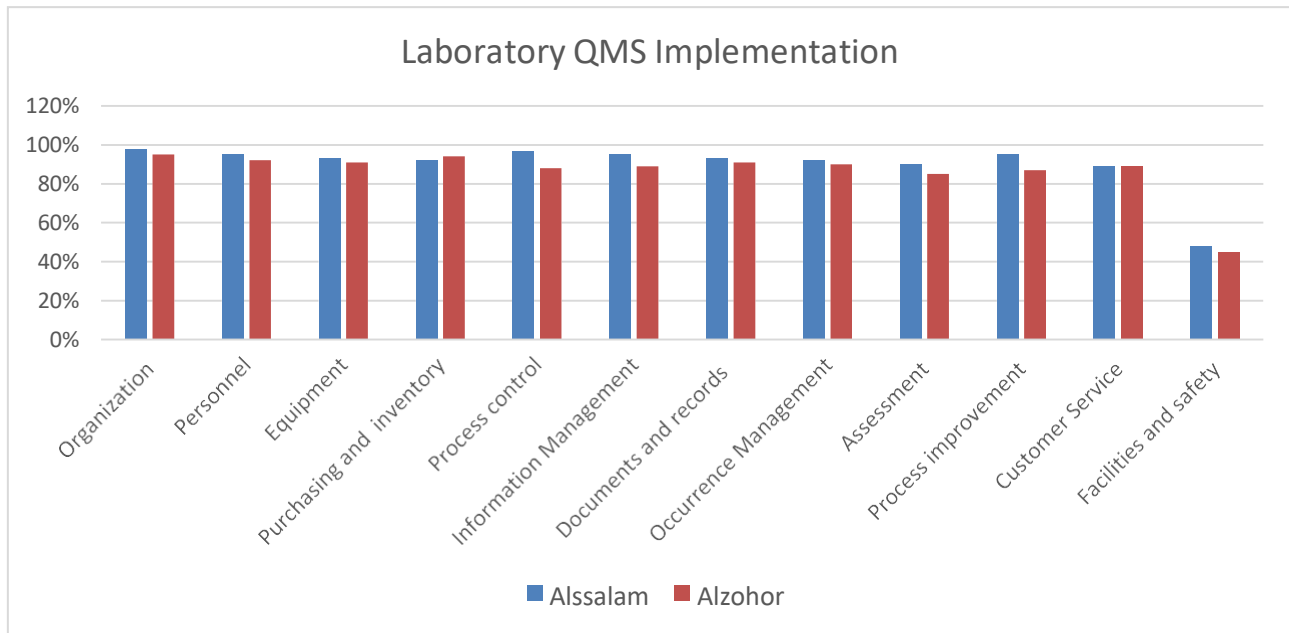
### (QS) review

(QS) achievement reviewing was drained 2 laboratories, that do advocacy of basic (QS) in its method and achieve GAHAR standards. As per (WHO) list as given within the Table one. The study assessment was made on the pictured parameters within the X axis and also the points got supported the implementation of existing (QS). the information is pictured in a very 100% paved vertical chart. The assessment detects that labs are achieving (QS) in its process disregard size of the lab. with completely different implementation percentage among QMS parts (Figure 2). There have been variations in utility and safety side.

**Table.1: WHO Quality System Essentials Checklist**

Quality system	Evaluation				Remark
	Y	P	N	NA	
<b>1. Organization and Management</b>					
1. Laboratory shall have the organizational and management structure and its relationship to any other organization with which it may be associated.					
2. Appointment of a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system.					
3. Laboratory management shall have responsibility for design, implementation, maintenance and improvement of the quality management system.					

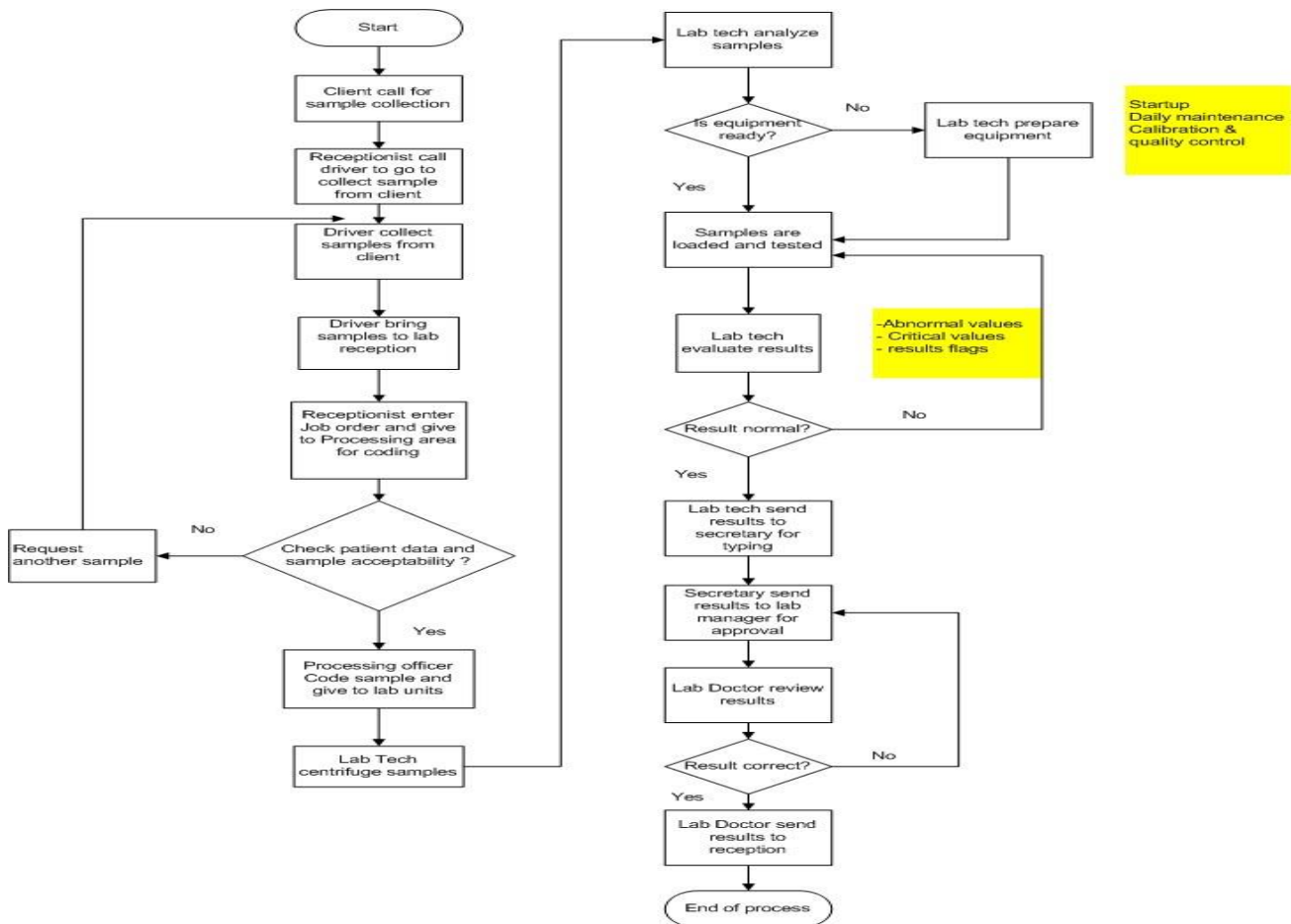
**Figure.2: Implementation Percentage of QMS Components**



### **Disregarding quality Implementation**

To achieve lab. effortless on its objectives achieving of QMS utility is important. The study found that the (QSMI)method wasn't achieved efficiently in each laboratory. A manually method wasn't advanced for supporting economical, efficient, prime quality method and acceptable lab. services no matter the dimensions of the lab. Quality standards weren't enforced within the lab. procedures or inner actions concerned in experimentation that uses devices, reagents, employees and alternative connected resources to stimulate the check results expeditiously. A registered check process wasn't ready in many labs. Tech makes the check by kit directions as a usual apply. alternative employees additionally learned identical apply and followed while not correct literature. Consciousness between employees is incredible weak concerning achievement of quality standards. Inner reviews weren't made to check the development and functioning of the lab.

**Figure 3: Flow Chart of the process flow inside the laboratory**

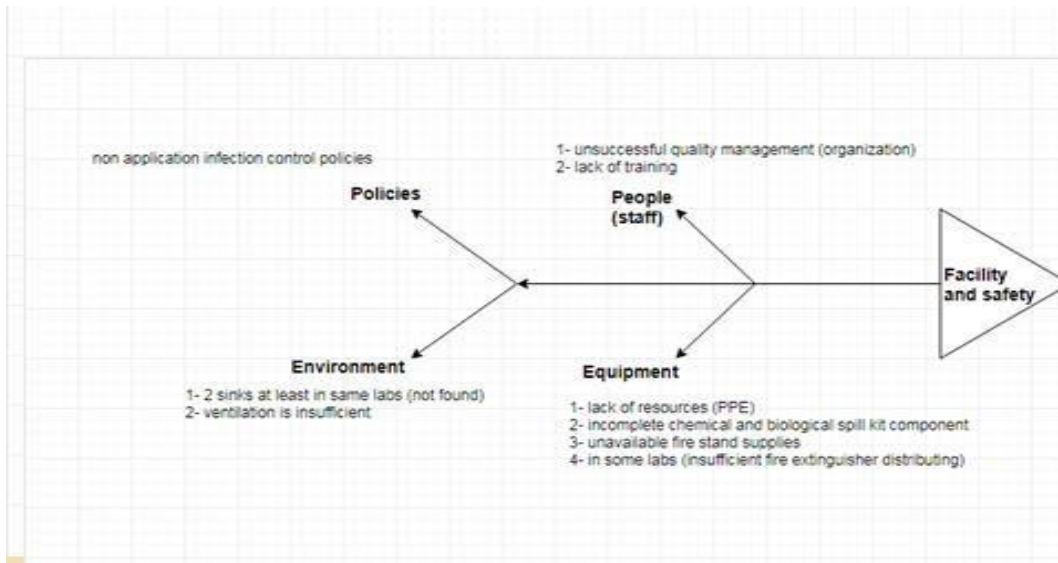


## Laboratory Safety

In context of quality management model, during our comparison between two labs, we found out the most common and important fatal problem is safety. The safety is very important due to possibility of communicable diseases transmission or general laboratory business effects as:

- loss of reputation
- loss of customer
- loss of profits

Root causes of the safety defects are summarized in the following fish bone (**Figure 4**):



### List of Causes for Safety Defects:

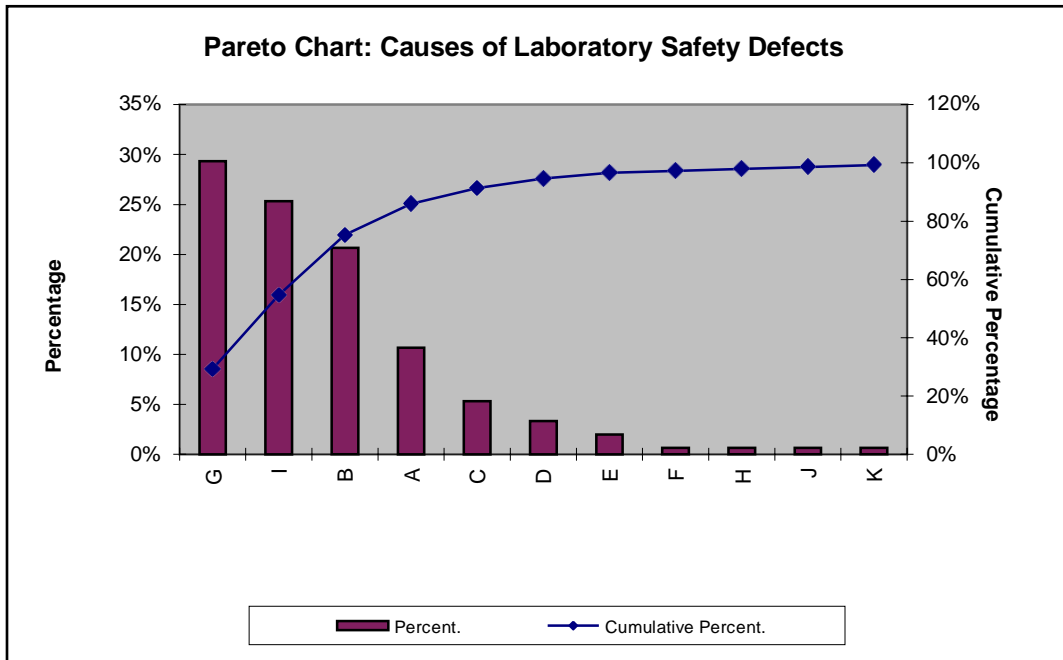
- A. poor extinguishers
- B. No appointed officer
- C. Lack of resources
- D. Poor implementation of IPC policies
- E. Incomplete spill kits
- F. untouchable fire stand provides
- G. Poor coaching of the workers
- H. Poor ventilation
- I. No safety policies
- J. Unsuccessful quality management organization

### Prioritization of Causes for Safety Defects:

Because restricted time, resources and workers, the team commit to confirm the important few causes of safety defects that if fastened properly can resolve eightieth of the protection issues in laboratories. information was collected concerning the frequency of the causes and tables was developed with the chances and accumulative percentages. Finally, Pareto chart was developed to assign the important few. The Pareto principle tells that for

several results nearly eighty percentage of implications return to twenty percentage of the reasons (the "vital few").[6]

Figure 5: sociologist Chart for the causes of safety defects:



Prioritized safety defects (vital few):

1. Poor coaching of the employees
2. No safety policies
3. No allotted officer

Improvement Cycle:

The Deming cycle is sustained quality development model conclude a logic serial of those 4 repeated paces and knowing as PDCA. In plan part, goal is to arrange for modification, to assess, and foresee the findings. In do part, arrange is done by dominating conditions. In check part the findings are examined. At the end, in act part, regulation works on boosting the process.

[8] Once we have a tendency to determine the causes of the protection

defects, PDCA cycle can begin to create and implement improvement for the matter.

**Figure 6: PDCA cycle:**



**1- Plan phase:**

During this phase we select our improvement actions according to the pre-determined causes and build **Gantt chart** to plan for our improvement steps:

Action	Responsible Person	Time for Implementation (per week)					
		The first seven days	The second seven days	The third seven days	The fourth seven days	The fifth seven days	The sixth seven days
Assign Lab Safety Officer	Lab Director						
Developing safety policies and procedures	Lab Quality & Safety Officers						
Contracting with external safety instructor	Lab Director						
Purchasing safety requirements	Lab Director						
Lectures for training	External Instructor						
Practical staff training	Lab Safety Officer						
Audit rounds by safety officer	Lab Safety Officer						

**Table 3: Gantt Chart for Safety Improvement**

## 2- DO Phase

During this phase we implement the plan on some units of the laboratory to pilot the improvement actions. The action plan was developed to implement the activities under the goal of decreasing the safety defects.

Goals	Activities	Responsible Person	Time Frame
Decreasing the defects of the laboratory safety standards	Assign safety officer	Lab director	2 days
	Training of the safety officer in external lab	Safety officer	2 weeks
	writing policies and procedures	Quality and safety officers	3 weeks
	Approving policies from authorized personnel	Lab, quality, and safety	1 week
	Training of the lab staff on safety PPs	Safety officer	2 weeks
	Conducting frequent audits to check for safety implementation	Safety Officer	4 weeks

## 3- Check Phase

During this part, a comparison was created between the amount of defect before and when implementation of the development activities:

- Review what has been enforced.
- Analysis of the results.
- verify the closeness to the target set, that is compliance with policies and documentation.
- Check any sudden resistance factors.
- Collect information to verify answer effectiveness.
- disposition to expand implementation.

## 4-Act Phase

During this part the actions were systemized supported the results of the check phase:

- If the modification doesn't reach achieving the goal, we'll repeat the previous steps.
- If successful, the modification is enforced over a wider continuance.
- continued the development method.

## Conclusion

Quality management isn't recent; creators outlined quality since eight decades. (QM) is applied for the lab because it is for producing and trade. A lab could be an advanced system and every one aspect should perform to realize quality. Reaching achievement of (Q) can differ by the native state of affairs. begin with changes which will be simply completed and have the largest effect. Although of those issues and defect that Facing in our labs, we are able to overcome these issues by that specialize in smart management (organization)that helps distinctive the coaching needs of staffing (employees) in step with WHO in laboratory quality management and watching quality management polices

Overall, within the current study known that the quality system wasn't effectively enforced within the laboratories, and also the study mentioned what might be done to boost and achieve (QS) in its observe. An additional elaborate analysis of registrations in (QS) and also the (Q) indexes ought to be made. sizable differentiation and asymmetry in terminology, identifying, achievement, measure and news action ought to be resolved so as to boost autonomous proof and its significance.

## Recommendations

Project advocate over there ought to become an everyday safety coaching for all the employees so as to form realization, interesting to achieve (Q) in labs



method, especially protection. The (Q) pointers ought to become used to benchmark, up actions. (QMS) in sanitary experimental labs explain requirement to understand ongoing commonplace necessities of (QSI) and continuity to enhance goodness of actions in labs, ease accreditation. Down in (QSI) give rise to descend goodness of actions then accreditation. More studies are required to visualize what percentage laboratory QMS elements were lined adequately in GAHAR standards.

## Summary

For achieving similarity, harmony in lab experimenting method, (ISO) publicize pointers like international measures. the opposite agencies (ILAC), (IAF). Through principles of procurations, lab releases examined outcomes, documented to become normal, distinctive, admitted everywhere globe. At nationalistic level, General Authority of health care accreditation associated Regulation (GAHAR) is an autonomous accreditation body. GAHAR promotes development and maintenance of excellent health care practices in adherence to normal exercises in experimenting and standardization, which is tech and administration necessities. The recent study recognized that the standard system wasn't effectively enforced within the labs, and therefore the study mentioned what may well be done to enhance and achieve (QS). An additional elaborate analysis of doc in (QS) and therefore (Q) pointers ought to be made. sizable differ, asymmetry in main terminology, declarations, achievement, measuring, reportage actions ought to be resolved so as to enhance autonomous proof, necessity.

## Abbreviations

**WHO:** World Health Organization

**QMS:** Quality Management System

**LQMS:** Laboratory Quality Management System

**QSI** : Quality System Implementation

**Q** : Quality

**LQ** : Laboratory Quality

**ISO** : International Organization for Standardization

**ILAC**: International Laboratory Accreditation cooperation

**IAF** : International Accreditation Forum

**GAHAR**: General Authority of Healthcare Accreditation and Regulations

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