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Continual Improvement in Laboratory Quality Management System of a Regulatory Laboratory in West Africa

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ABSTRACT

Medicines quality monitoring and quality control are essential components required to deliver health value to the people. These will also improve access to quality assured medical products that are safe for intended use. Quality Control Laboratories play an essential role in strengthening health systems in West Africa. Their role in providing excellent testing services that ensures correctness, trust, and consistency of laboratory test results is key in assuring product quality. Improving the laboratory Quality Management System (QMS) will require concerted and coordinated efforts by all interested parties in establishing relevant, continual improvement plans/strategies that will sustain and improve all components of the laboratory QMS. The challenge of substandard and falsified medicines in West Africa requires not only quality assurance strategies that reiterate quality by design, but also quality control activities for effective and consistent quality monitoring of medicines in circulation. A quality management system (QMS) enables creation of significant value while also ensuring that concrete and consistent improvements are made on a regular basis. The development and preservation of value in the process, people, and leadership helps to achieve goals and improve performance (Brewoor & Pawar, 2010). Human resource is the most important component in the Quality Control Laboratory. Their attitude to work and life affects laboratory QMS and productivity. Establishing a QMS without creating the corresponding organizational quality culture and key behavioral requirements will be counterproductive. This study attempts to critically examine the concepts of continual improvement in a Laboratory Quality Management System of a regulatory laboratory in West Africa. This study provides insight on the current status of laboratory QMS, components of the QMS, the improvement pattern, the enablers of continual improvement, and possible challenges/gaps. Data was collected from laboratory records of internal audit, non-conformances, corrective action, and management review meetings reports. After analyzing the findings of this inquiry, it was concluded that, although the laboratory had implemented and established all components of QMS, there were identified gaps in improvement of laboratory QMS on a continual basis. Fulfilling standard requirements is not sufficient to establish and improve a system. Intentional building of quality culture in the laboratory is paramount in ensuring continual improvement. The study showed that quality audits and management review meetings (MRM) failed to improve the QMS as expected. There was increased reoccurrence of non-conformities despite improved knowledge and management commitment. The observed non-conformities increased by 200% within four years and the annual implementation rate of management review action plan was 36.6%, which is below average performance. The laboratory can explore other enablers of continual improvement that are not documented in standard literatures employed in establishing laboratory QMS. These include building organizational quality culture, investing in human capital attitudinal and behavioral changes, establishing a reward system, improving remuneration, and developing a robust business plan for the laboratory to operate as a viable business venture.

Keywords: laboratory, continual improvement, quality control, quality monitoring, Quality Management System (QMS)

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Introduction

As resource limited countries struggle to meet the United Nations Millennium Development Goals and ensure adequate provision of the right medicines for treatment, these unindustrialized, resource-limited countries also urgently need to build and support an efficient national laboratory as part of strengthening their health systems (Nkengasong et al., 2009). Over time, health organizations have increasingly prioritized the quality of laboratory services by building strong structures, implementing quality management systems, and engaging in other value-added activities to improve quality (Gima, Deress & Adane, 2020).

A strong Quality Control Laboratory provides a regulator with the confidence needed to make decisions, or evidence-based actions, to protect patients/public from poor quality medicines. Building a culture of quality and continual improvement will eliminate inefficiencies and make processes more consistent, reliable, and reproducible.

Decline and fluctuations in quality improvement in the laboratory, if not checked, can lead to analytical delays, loss of accreditation, poor decision making by managers, poor performance in proficiency testing, data integrity, and other quality related problems amongst others. All of these threaten the existence and sustainability of the QMS and access to right quality of medical products.

Using a laboratory in a West African Regulatory Authority, this study critically examined the current status of laboratory QMS, components of the QMS and the improvement pattern using some quality indicators that facilitate continual improvement. Quality culture is created after a long while but when the laboratory quality management system is not progressing in a continual manner Laboratory test results will not be reliable (Meadows, 2008).

A well-designed, robust overall governing mechanism that connects positions of authority with defined tasks, benefits, and self-actualization programs is required for an efficient system. Furthermore, promoting seamless collaborative efforts between different departments is critical to achieving corporate goals and objectives.

The National Regulatory Authority's (NRA) laboratory testing regulatory function is designed to ensure that the NRA can examine the quality of medical products by performing quality tests on them in specific instances. Testing may also be required for products that have been the subject of a complaint or report, or for products that are being investigated as a result of an adverse event. Laboratory testing is also used as part of the market surveillance role to evaluate and confirm the quality of medical items placed on

the market, as well as to detect substandard and fraudulent medical products. In order to do this product testing, the NRA must have access to suitable laboratories where these tests can be performed. A laboratory under the control of the NRA or a governmental laboratory is the best option if a country has all of the necessary resources (World Health Organization [WHO], 2021)

However, improving a laboratory Quality Management System in a resource-constrained country is not an easy task considering the enormous human, material, and financial resources required to assure the validity of test results. All improvements involve changes, but not all changes are improvements. Quality improvements are a result of collective and continuous hard work embraced by all who produce positive changes in health, the health system and professional growth.

The long-term objective of improving laboratory output is for the laboratory to strategize, plan and analyze methodically at defined intervals and evaluate the growth rate to improve patient health outcomes (Nevalaime et al., 2000). Specifically, ISO 9001 offers a standard to increase all processes productivity and value (Su, Kao, & Linderman, 2020).

The Economic Community of West African States (ECOWAS) with about 17 countries was reported in 2015 to have a population above 349 million, while the World Bank estimated the population of the region in 2018 to be 367 million. When the quality of medicines in any of the countries is compromised, the ECOWAS region's health systems are impacted negatively.

In view of this, there is a pressing need to ensure that laboratory systems in the region are capable of verifying labeled claims, identifying suspected adulterants, sub-standard, and falsified medicines, and making the necessary regulatory decisions on medicines' quality and safety. Strengthening the laboratory QMS guarantees that standards are maintained and that they continue to improve in order to consistently give trustworthy test results and, ultimately, to protect the public's health.

A quality management system is established by implementing ISO 9001:2015, which refers to the global tenets and principles used in implementing the quality management system. Other supporting principles are contained in ISO /IEC 17025:2017 which is the International Standard requirements for testing, calibration, and sampling laboratories.

In a quality control laboratory, ISO/IEC 17025:2017 is the required standard for establishing and implementing laboratory QMS (Wadhwa, Rai, Thukral, &

Chopra, 2012). Accreditation programs evaluate laboratories in line with recognized and agreed principles of practice and quality criteria, giving a valid justification for client trust and endorsement that the laboratory output is reliable, correct, and confirmable. Laboratory accreditation provides a standard reference of comparison for the institution, application, and sustenance of the laboratory quality management system (Gershy-Damet et al., 2010).

The Laboratory accreditation procedure conveys certified recognition and approval, which validates that the laboratory has shown verifiable proficiency, skill, and ability to perform the identified scope (Wadhwa et al., 2002). Accreditation engineers support quality by producing opportunities for the laboratory to reflect on its non-conformities, which will ultimately occur in the system when there is an absence of effective continuous monitoring (Wadhwa et al., 2012). However, laboratory accreditation is not an end in itself, but rather the starting point of the endless journey of continual quality improvement.

Quality Management System

Quality glossary defines Quality Management System (QMS) as a structured documented system employed in realizing an organization's system-quality goals, targets, principles and strategic plans, policies, and objectives. A QMS guides, organizes, and strengthens processes of an establishment, thus enabling it to satisfy the needs and expectations of all interested parties and consistently enhancing value and productivity

All employees occupying various positions in an establishment should be given incentives, be retrained and be re-oriented on a regular basis because realizing the quality goals can only be actualized if all staff are inspired and encouraged to give their best. Consequently, in accomplishing sustainable growth in quality, the leadership must embrace this transformational concept because they possess more influence and authority in actualizing it (Liebesman, 2003).

At the very onset of the 1980s, William Edwards Deming, one of the early advocates of quality management, fashioned 14 points on quality management which highlighted the importance of quality management in facilitating quality and outputs of companies (Liebesman, 2003). Deming's 14 points empower organizations to provide programs that promote hard work and create organizational culture, values, and principles where all employees are enabled to have a positive work attitude and organizational loyalty for their benefit and that of their employer and clients (Mawhinney, 1992).

Deming's 14 Points for Continual Improvement of Organizational Performance (Mawhinney, 1992):

1. Build an enduring vision that will facilitate efficient output with the purpose of remaining relevant and sustaining profitable growth and employment;
2. Embrace innovative principles and ideas. Leaders of organizations must propagate transformational strategies, appreciate the difficulties and their roles in facilitating solutions;
3. Encourage quality by design from the onset, and reliance on examination only to attain quality should be abolished;
4. Develop a quality culture and healthy engagement policy with external service providers by having a sustainable and reliable association with them and also considering quality and cost in deciding on affordable price for the product;
5. Continually advance and ensure an enduring efficient organization with consistent increase in output and reduced expenses;
6. Establish a hands-on capacity building program;
7. Provide the required guidance and direction by establishing managers to oversee and administer every aspect of the organization in order to achieve improved performance;
8. Exterminate and remove anxiety and panic to facilitate all to function and perform well;
9. Dismantle and erase communication bottlenecks between sections of the organization so that risks and possible challenges associated with the work can be readily identified;
10. Management should establish measures that will stop unhealthy competition and undue pressure on the staff by refraining from using cohesive statements that push staff and demand perfection and increased performance from them since relying solely on increased performance and quality of work by staff cannot increase output;
11. Replace and have back-up supervisors and eliminate allocation of job portions for low level employees; also change the system and concept of focusing on just actualizing organizational targets and measuring individual performance;
12. Get rid of things that hinder employees from having a sense of self-worth and importance and managers whilst discharging their duties

should lay more emphasis on quality rather than quantity of output, also eliminate obstacles that deprive leaders and workforce of benefits and removal of the yearly performance evaluation to achieve goals;

13. Establish a robust scheme for learning and personal progression;
14. Empower all staff to be part of the change process because it is the responsibility of all.

Figure 1

The Seven Quality Management Principles.



Note. These principles are essential in implementing a quality management system.

Principles of Quality Management System

A Quality Management System is deliberately designed to progress and develop to satisfy the growing demands of an establishment. A Quality Management System is the major means for service providers, like engineering industries, to consistently measure how the services provided by them meet the needs and expectations of customers, even as globalization is being introduced (Brewoor & Pawar, 2010).

The primary objective of QMS is to develop a systematic pathway that identifies and protects the overall interest of all parties to the benefit of the organization and its customers (Flett, 2001). Thriving and prosperous establishments lay great emphasis on sustaining growth and have a constant drive to enhance productivity and attain greater heights. This is

necessary to preserve gains and respond adequately to situational context of the organization and develop innovative breakthroughs ("7 Principles of ISO 9001:2015," 2015).

The ISO 9000 family provides a group of universal guidance documents with details of norms and expectations for a Quality Management System. The documents establish quality management concepts and values. A quality management system is made up of vital rules, practices, and methods necessary for a body to achieve its goals and progressively and efficiently acquire better skills and competencies. (Wilson, Graham, Robertson, & Lennard, 2018).

There are seven management principles that guide implementation of ISO 9001:2015 as shown in Figure 1:

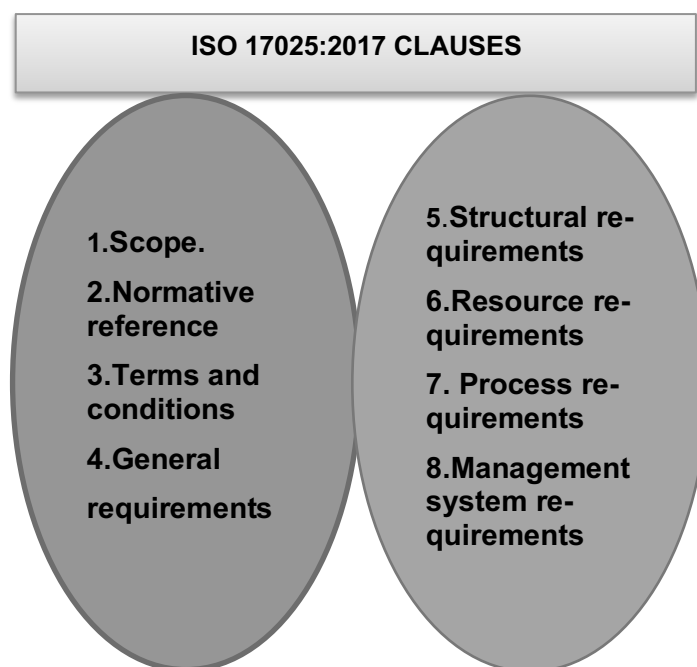
1. **Customer Focus** - meet and exceed customer requirements and expectations;
2. **Leadership** - institute a unified goal, give direction and develop right enabling environments for achieving organizations' quality objectives;
3. **Engagement of People** - knowledgeable, experienced, authorized and dedicated people produce quality and efficient services.
4. **Process Approach** - reliable, dependable and reproducible results through well managed interrelated processes;
5. **Improvement** - to maintain organizational performance and develop innovative prospects for improvement;
6. **Evidence-based Decision Making** - decision making centered on facts, quality data evaluation (for greater objectivity) and confidence;
7. **Relationship Management** - managing the needs of all interested parties to optimize organizational performance.

The quality management principles are grounded in ISO 9001:2015 standard (ISO, 2005, ISO,2015). The degree of application of ISO 9001 in an establishment determines the maturity level of the quality management because ISO 9001 encompasses everything needed for effective implementation. It also significantly improves the performance of the testing laboratory and gives the customer confidence in the quality of the results of laboratory tests (Konovalova & Popova, 2010).

Laboratory Quality Management System

A laboratory quality management system is an organized, logical and established interconnected structure with tasks and actions designed to create and regulate an analytical course from beginning to end. This includes assessments and handling of supplies, personnel, and finance, which provides a sustained and progressive growth; resulting in reliable quality outcomes (Carey et al., 2018). The most successful approach of attaining, sustaining, and improving QMS suitability and correctness is for the laboratory to implement QMS in line with the requirements of ISO 17025: 2017 (Jadaun, Saklani, Dixit, Jain, & Singh, 2016). ISO 17025, 2017 has eight (8) requirements as presented in Figure 2.

Figure 2
ISO 17025:2017 Clauses



Note. Implementation of clauses 4 to 8 is mandatory in laboratory quality management system (ISO, 2017).

The establishment of a laboratory QMS is achieved by planning an effective quality assurance (QA) program. This enables the laboratory to carry out its testing activities efficiently and ensure that the needs of the customers are met consistently and, thereafter, the laboratory's performance is measured against a standard. Subsequently the system progresses and improves in a continual manner. Accreditation sustains and supports quality by assuring that the laboratory has a chance of examining its activities to identify non-conformities, which happens unnoticed, especially in the absence of continuous monitoring (Wadhwa et al., 2012).

The central purpose of a laboratory quality management system is generating appropriate, defined, correct and verifiable testing outcomes and fulfilling clients' requirements and expectations (Jegade, Mbah, Aminu, Yakubu, & Torpey, 2015). In ensuring the validity of test results, monitoring measures are planned and data from monitoring activities are analyzed to improve laboratory activities (ISO, 2017). One of the measures includes participation in proficiency testing (PT), also called External Quality Assessment Schemes or Interlaboratory Comparison (ILC).

One of the key constituents of a laboratory quality management system is the External Quality Assessment (EQA) program. The major goal of EQA is to create strong expertise consistently confirming that laboratory reports align with standards, enhance quality of clinical outcomes, facilitate transcription of test reports between laboratories irrespective of the techniques, and identify mistakes in quality control testing (Arnaud et al., 2020).

Laboratory accreditation provides third party endorsement after due evaluation of the laboratory system against official recognized standards. The establishment and application of laboratory standards, confirmed via the accreditation program, guarantees customer trust and confidence on the laboratory services (Gershy-Damet et al., 2010).

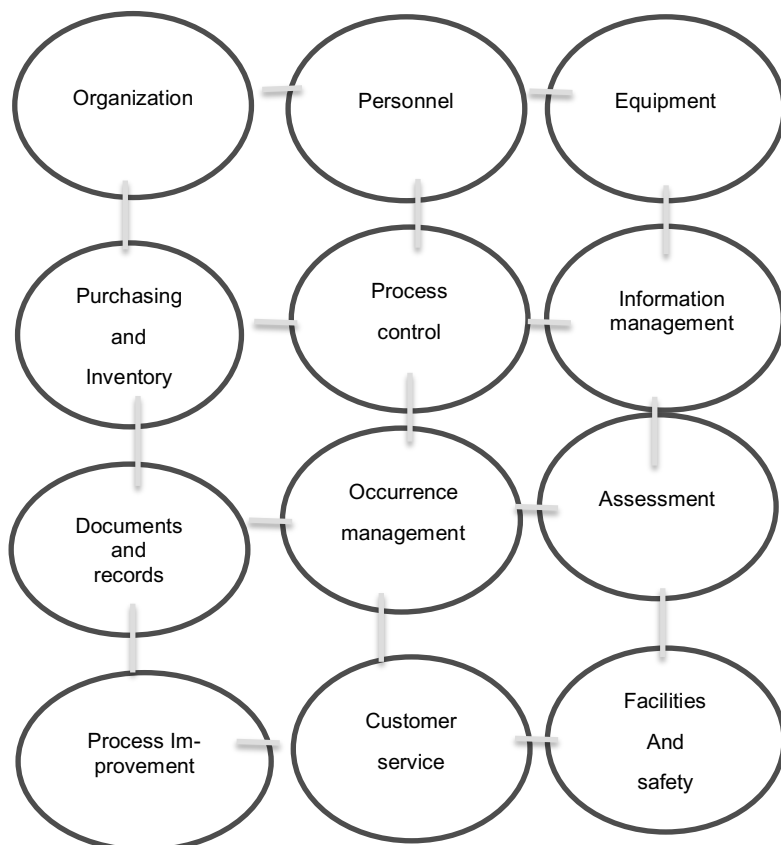
To ensure that productivity is always enhanced on a regular basis, right judgement and pronouncements, based on reliable, appropriate, and precise information need to be made. Information that is true, apt, legal, and significant is the core of quality management (Koehler & Pankowski, 1996).

The laboratory generates and documents a wide range of records that is organized and controlled to guarantee reliability, safety, identity and source. It is worthy to note that regardless of the control measures employed by the laboratory (automated or physical) to assure the validity, reliability, and accuracy of created records, in the laboratory process flow from sample receipt to test result production, the standard, rules, good practices, and other procedures for safeguarding the records are regarded as critical in preventing unauthorized usages, record alterations, threat, and unintended release of records (Carey et al., 2018).

The goal/aim of the laboratory quality management system is to establish the concept of "right first time," present reliable test results, guarantee data integrity, competence, and productivity, fulfill clients' needs and expectations, deliver capacity building prospects, and enhance laboratory integrity (Martin, Hearn, Ridderhof & Demby, 2005). The laboratory is a multifaceted, organized system comprised of many

interrelated activities and staff with varied competencies; thus, there is need to ensure delivery of efficient services on a continual basis. This can be realized by an enhanced degree of consistency, precision and correctness. To successfully accomplish this, the holistic approach, as presented in the ideals of a quality management system, is essential for accomplishing great tasks in the laboratory (World Health Organization, 2011).

Figure 3
Twelve Quality System Essentials.



Note. Twelve (12) Quality System Essentials as shown in Figure 3 are the pillars that ensure building an efficient QMS (World Health Organization, 2011).

Continual Improvement (CI)

Continuous quality improvement (CQI) is a method employed by organizations to implement, establish, and sustain quality. Consistently highlighting and evaluating probable sources of quality defects and subsequently implementing corrective actions will facilitate prompt and timely identification and salvaging of dwindling quality performance (Westcott & Duffy, 2015).

Continuous improvement is the real idea that drives Total Quality Management (TQM), facilitated by a robust response mechanism. A prompt response

mechanism, which includes response to an occurrence in assigned activities and, consequently, sustainable growth and awareness through demonstrated skills, are constructive gains which can only be accomplished through this response mechanism (Flett, 2001).

Continuous quality improvement (CQI) and total quality management (TQM) are a current quality improvement approach that reiterates leaders' responsibilities in supporting quality as a culture, establishing quality objectives and effectively communicating these objectives, advancing productivity in the organization and thus stimulating leaders to consistently focus on quality component of their activities (Yank, 1995).

Some improvement protagonists propose with certainty that initiating activities that will progress organizational processes is much easier than sustaining these initiatives, especially in the face of dwindling zeal and passion (Silver et al., 2016).

CI is a practice that involves unending transformation. Transformation requires considering likely hazards and threats in a laboratory and the ability to develop methods to address these threats and how they influence the system. By presenting a universal outlook to different forms of transformations, QMS actually promotes system thinking.

Information dissemination is a major element of CI scheme. To reap the gains and accomplishments of CI, it is essential to give timely and up-to-date information to all with respect to the objectives of the CI program, and establish a platform for staff to ask questions as appropriate (Carey et al., 2018.)

Some of the ways for improvement in the laboratory processes are listed below:

- i. quality objectives and its performance report
- ii. failure mode effect analysis (FMEA)
- iii. internal Audit
- iv. bench marking
- v. statistical process control
- vi. 5S (sort, store, shine, standardize and sustain) (Lakhe, 2017).

Analysis of the data for continual improvement will include the following variables:

- i. key performance indicators, objectives, management reviews;
- ii. customer feedback, complaints, orders, and satisfaction surveys;
- iii. conformity to product specifications, rejections, acceptance under concession;

- iv. characteristics and trends of processes and products;
- v. performance of externally provided products, services and processes;
- vi. break down records of machineries and equipment;
- vii. measurement and monitoring data (Lakhe, 2017).

The current development in quality improvement highlights and stresses the need to support activities that create quality improvement, rather than embarking on assessments to identify and rectify mistakes (Plebani, 2003). The prerequisites for starting continuous improvement includes detecting faults, challenges, and difficulties, as well as encouraging people to take necessary actions to address them (Karapetrovic & Willborn, 2001).

Process improvement are results of planned interventions. These interventions enhance activity unlike unplanned efforts that merely deal with new problems and difficulties.

A continuous process improvement cycle is a structured and systematized activity, or group of activities, geared towards steady enhancement of processes in an organization. Methods deployed to facilitate the drive for process improvement include; Six Sigma, Lean, benchmarking, and incremental and breakthrough approaches (Westcott & Duffy, 2015).

Discrepancies in a process can be detected and resolved using the six sigma, which is a systematic technique mainly expressed as sigma level or defect per million opportunities (DPMO). Six sigma is a continuous process improvement procedure that enables almost 99.9% performance in the establishment's processes.

The Define, Measure, Analyze, Improve, Control (DMAIC) procedure is deployed as an instrument for improvement used to detect and remove the root causes of deficiencies using the listed development and execution stages:

- i. **D:** Define what has gone wrong or the prospect of making progress;
- ii. **M:** Measure how well the current method has been implemented;
- iii. **A:** Analyze and review the method to identify reasons for reduced productivity and decide to optimize or restructure the method;
- iv. **I:** Improve the manner in which investigations for reduced productivity are conducted;
- v. **C:** Control the enhanced and optimized method to sustain achievement

(Westcott & Duffy, 2015).

The core phases in the application and appraisal of strategies to enhance quality are explained by the Plan-Do-Check-Act/Plan-Do-Study-Act (PDCA/PDSA) cycle, which is identical to Process approach as contained in ISO 9001:2015 and Quality Management Principles. An assignment can be observed and evaluated with PDCA, or even deployed in directing the course of a new venture. PDCA is a series of linked collaborative actions for continual enhancement centered on a logical, systematic way of initiating, deploying and evaluating outcomes of change and executing the right plans to accomplish organizational objectives (Kryzanowski et al., 2019).

Internal Audit

An audit is a standardized, recognized, efficient procedure used for procuring an accurate appraisal of proof to establish the rate at which the audit standard requirements and principles are met. The purpose of an audit is to evaluate the productivity, proficiency, and value of the management system, which can be helpful in detecting non-conformities and deploying effective mitigation plans (Domingues, Sampaio, & Arezes, 2011).

The ADRI system (Approach, Deployment, Results, Improvement) is one of the age-old established and designed quality methodologies. The system has the initial three phases closely related to the three periods of quality assessment. The three steps clearly illustrate that quality assessment can ultimately enhance quality (Woodhouse, 2003). However, the organizational culture determines, to a large extent, how well the quality audit can achieve this objective.

Clause 9.2 of ISO 9001:2015 requires that an organization conduct scheduled internal audits to verify suitability of the organization's QMS and compliance to the contents of this global standard, ensuring that it is adequately applied and sustained. Scheduled meetings to appraise the quality management system are conducted by the top management of the organization to ensure that it collaborates the long-term plans and is still relevant, fit for purpose, appropriate, and useful. The meeting reviews extent of implementation, achievements, and failures using data from the following activities:

- i. customer fulfillment assessment, communication, and response from applicable clients;
- ii. percentage of implementation of the quality objectives;
- iii. process productivity and output performance;

- iv. departures, deviations and improvements to remove undesirable situations;
- v. analysis and evaluation of results;
- vi. assessment findings;
- vii. the appraisal ratings of external providers;
- viii. sufficiency of process inputs;
- ix. the appropriateness of mitigation plans used in tackling address risks and opportunities;
- x. probable areas that require upgrade or advancement.

The extent of implementation of outcomes of preceding management reviews, and any pertinent alteration in the context of the organization that significantly impact the quality management system, are likewise appraised and acknowledge (ISO,2015). The output of the management review meetings is deployed as action plans for continual improvement and growth of the system. Quality Culture

A complete change in the culture of the organization and uninterrupted active involvement of every one of the methods for quality enhancement are the challenging activities required for institution of TQM (Irani, Beskese, & Love, 2004). Technology, economic resolutions, governance, corporate policy, and planning of activities are indeed essential components associated with quality culture (Ehlers, 2009).

The following points are very crucial in enforcing cultural change:

- i. Ensure quality is ingrained in the rules, procedures, and practices of the organization.
- ii. Communicate to all the significance of quality in realizing organizational goals.
- iii. The demands and expectations of clients must be recognized by all categories of employee.
- iv. Measures that will consistently lead to progress should be embraced by governance.
- v. Incorporate the expectations of clients in developing corporate strategies.
- vi. Deploy appraisal rating programs that have client perception as a key component.
- vii. Establish robust information sharing matrix and platform.
- viii. Customer communication should be fostered.
- ix. Create and build client friendly practices and principles (Irani et al., 2004).

Quality management should not be a passive implementation and application of requirements that focuses on, or is seen only as, a component of a third-party accreditation scheme. Corporate bodies that have established quality culture build quality into all routine procedures and practices (Wilson, Grahah, Robertson, & Lennard, 2018). Quality culture emphasizes norms, customs and philosophies of an organization as they perform their routine daily work in line with laid down procedures, rules, protocols, and code of practice (Ehlers, 2009).

Generally, four quality management practices are observed in order to adapt quality practices and progressively increase organizational productivity. The practices include collaboration, capacity building, monitoring, and evaluation of procedural activities. Governance and organizational commitment are excluded because there is a thin line between manipulation and consideration. According to Wu, Zhang, and Schroeder (2011) all quality directives have four pivotal factors:

- i. guidance, directions, and participation of the organization;
- ii. preparedness and engagement of workers;
- iii. readiness of all to imbibe new means and method of discharging their duties;
- iv. capability and re-education of employees to perform and take charge of their responsibilities (Andrade & McDowall, 1998).

At the very core of total quality culture is a shared vision with shared values and objectives in every dimension of the P-pyramid. The P-pyramid has 6 components with performance at the tip of the pyramid and philosophy (principles) at the base. The others include policies (procedures), program (people), and purpose (profit). The P-pyramid shares values that are implemented in quality culture (Batten, 1992). Quality comes from having elements of the P-pyramid understood and applied at all levels in the organization.

METHODS

action plans implemented annually. The laboratory records were obtained from an ISO 17025:2017 accredited regulatory laboratory in West Africa.

Table 1
Observed Non-conformances in Internal Audits. 2014, 2016 – 2019

Year	Total number. of non-conformances	Number of non-conformances addressed	Number of non-conformances not addressed
2014	106	103 (97.2%)	3 (2.8%)
2016	153	104 (68.0%)	49 (32.0%)
2017	150	111 (74.0%)	39 (26%)
2018	254	168 (66.1%)	86 (33.9%)
2019	327	170 (52.0%)	157 (43.0%)
Sum	990	656 (66.3%)	334 (33.37%)
Mean	198	131.2	66.8

Note. Table 1 shows the observed Non-Conformances from Laboratory Quality Internal Audit.

Table 2
Occurrence Pattern of Non-conformances Observed in Internal Audits

Year	Inadequate document control	Procedural deviation	Facility limitation	Non-adherence to good documentation practice	Inadequate procedure	Inadequate knowledge of the procedure	Others
2014	*	8	15	35	26	*	21
2016	*	12	27	29	25	*	21
2017	32	19	35	24	14	11	15
2018	33	29	50	40	34	23	25
2019	17	28	20	34	18	16	5
Sum	82 (for 3 years)	96	147	162	117	50 (for 3 years)	87

*Was not captured because the category was not in existence then.

Note. Table 2 presents the categorization of observed Non-conformances from 2014 to 2019. The seven identified categories were trended to identify the reoccurrence pattern of the NCs. 2015 data was not available.

Table 3
Number of Management Review Meeting Action Plans 2014 - 2018

2014	2015	2016	2017	2018
12	8	9	11	19

Note. Table 3 is a representation of the outcomes of the management review meeting from 2014 to 2018 indicating the number of action plans to implement for continuing improvement of the quality management system.

Table 4
Implementation of Management Review Meeting (MRM) Output Action Plans (2015 - 2019)

2015

No. of action plans implemented (X)	5 (41.7%)
No. of action plans not implemented (Y)	7
No. of action plans partially implemented(Z)	0

2016

No. of action plans implemented(X)	2 (25.0%)
No. of action plans not implemented (Y)	6
No. of action plans partially implemented(Z)	0

2017	
No. of action plans implemented (X)	2 (22.2%)
No. of action plans not implemented (Y)	5
No. of action plans partially implemented (Z)	2
2018	
No. of action plans implemented (X)	4 (36.4%)
No. of action plans not implemented (Y)	0
No. of action plans partially implemented (Z)	7
2019	
No. of action plans implemented (X)	11 (57.9%)
No. of action plans not implemented (Y)	6
No. of action plans partially implemented (Z)	2

Note. In table 4 the 2014 MRM had 12 action plans. Out of this only 41.7% (5) of the planned actions were implemented and in 2015 48.3% (7) of the plans were not implemented.

3. Results and Discussion

It is only in being aware that the growth of a Quality Management System is not continual that steps can be taken to improve it. The results obtained from the study showed a steady increase in internal audits observed non-conformances (NCs) from 106 in 2014 to 254 in 2018, as shown in Figure 4. When an organization intends to be customer focused and improve on its capacity to meet the needs and expectations of its clients, a vital strategy is essential for the implementation of Internal Audit procedure (Westcott & Duffy, 2015). The observed leap of more than 200% from the 2014 observed NCs to the current 2019 number of 327 (Table 1) does not show that there was an improvement. The Quality Audit has failed to cause continual improvement of the laboratory QMS. Why? This could be attributed to many factors which include attitude of staff, inability to adapt to changes, exhaustion due to heavy workload, staff perception of management attitude towards their welfare, absence of quality culture, un-conducive work environment, and poor leadership.

In 2019, the recurrence of NC category "inadequate procedure" showed a 69% decline when compared with the 2014 data. The other categories, inadequate document control, procedural variation, facility limitation, non-adherence to good documentation practice, insufficient knowledge of the technique, and others, all increased between 2014 and 2019 (Table 2). This shows that the cause of the deviations and recurrence of NCs was not due to absence of the right or adequate procedure but rather the attitude and culture of staff and management.

Organizational performance, most importantly the realization and achievement of quality goals, objectives, and plans, are influenced by quality culture (Friedli et al., 2018). Unbiased and collaborative strategies are key to providing the necessary and very important progress required to achieve major and visible outcomes in laboratory performance (Andrade & McDowall, 1998). The compliance level of implementing corrective actions to address NCs declined by 52.0% from the 2014 score of 97.2% (Figure 5). This can be attributed to loss of interest in the system by staff, weak management, and control strategy.

ISO 17025:2017 clause 7.10.1 requirements on handling nonconforming work states that the laboratory should have a procedure for handling non-conformities when there is a departure from set standards in any step of laboratory processes. Established measures required to satisfy the needs and expectations of the clients and also address possibilities of reoccurrence of procedural deviations, failures and great uncertainty in the ability of the laboratory to comply to standards should be put in place.

ISO 9001:2015 clause 10.2.1 states that when a non-conformity occurs, the establishment should analyze the relevance of identifying applicable solutions by abolishing the root cause of the failure or deviation to prevent it from happening again and implementing the corrective actions as appropriate. The inability to implement corrective actions for observed non-conformances has negated the goal of

the CAPA sub-system, which ensures that when processes are out of control, corrections and/or corrective actions are implemented to ensure that the processes are continually improved.

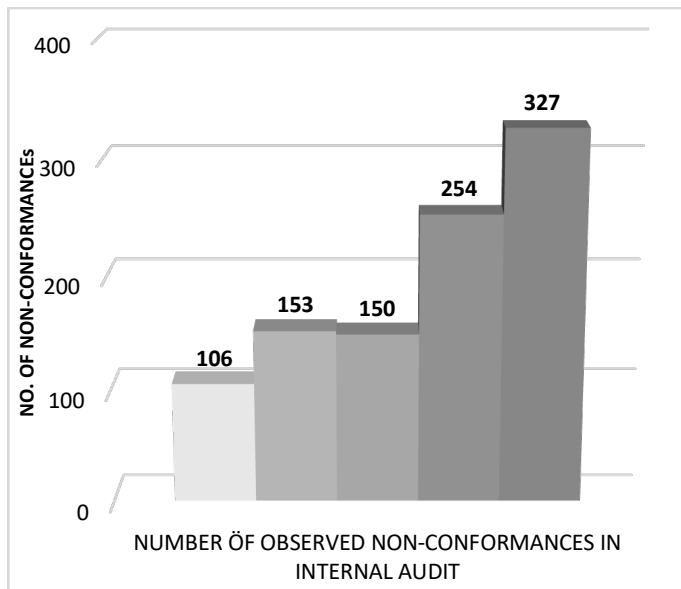
Structuring and building laboratory quality objectives is achieved by the establishment and implementation of quality assurance programs which ensures quality by design in the entire laboratory workflow-from input, activities and outputs, not just the output. This model empowers all laboratory personnel to work towards satisfying their customers (Hanlon, 1996). As shown in Table 3 and Figure 6 action plans are identified annually in Management Review meetings, however there are different levels of implementation of identified actions.

Both Figure 7 and Table 4 show MRM action plans implemented, not implemented, and partially implemented from 2015 to 2019, while Figure 8 shows the Implementation of Management Review Meeting Action Plans from 2015 to 2019. There is an average of 36.6% implementation for the five years with 2019 having the highest of 57.9% implementation rate. The actions plans of the preceding year are reviewed in the current year. The percentage of total action plans implemented annually was less than 50% for three consecutive years until 2019, which had 57.9% performance. The implementation rate of agreed Management Review Meeting Action Plans declined steadily and suddenly improved by 21.5 % from the 2018 figure (Figure 8).

This inconsistent pattern in addressing and implementing MRM action plans shows inadequate commitment by management in ensuring sustainable growth and improvement of the QMS. With less than 50% of action plans implemented consecutively for three years, management should reevaluate resources committed to implementation of QMS to ensure processes are adequately resourced to provide desired outputs and outcomes.

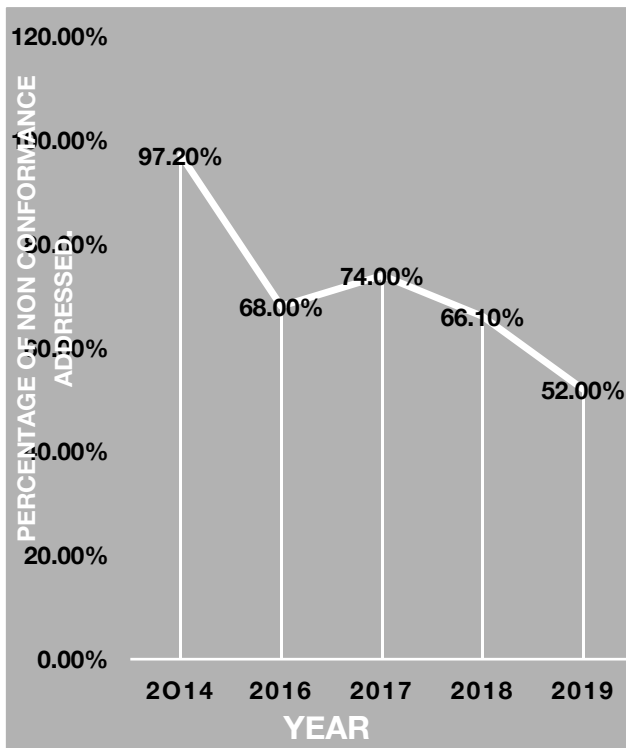
Figure 4

Non-conformances Observed in Internal Audit: 2014-2019



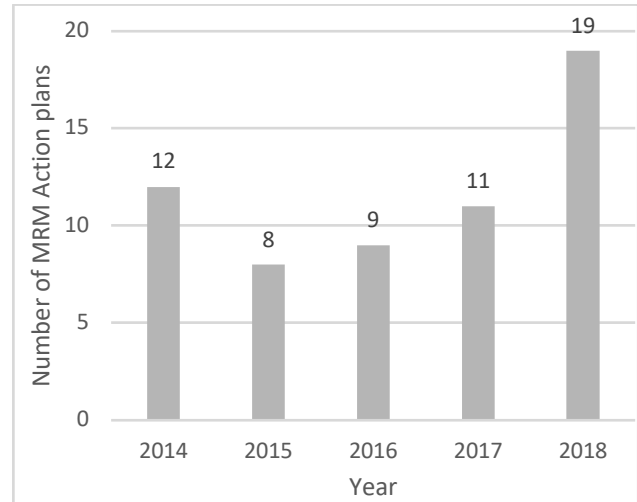
Job satisfaction, good remuneration, robust reward system, quality culture and running the laboratory as a viable business entity using the business model innovation are possible enablers of continual improvement that can be explored. The business model innovation is about creating value for the organizations, customers and society. (Osterwalder & Pigneur, 2010). Developing and deploying the nine constructive pillars of the Model will guarantee this. The nine pillars are the crucial success factors that need to be identified and explained in order to justify how a company develops and provides value. The pillars include- key partners, key activities, key resources, value proposition, customer relationships, customer segments, channels, cost structure and revenue streams. The pillars will aid in identifying client segment, the innovative service intended to attract clients, network, client engagement and interaction, income stream, main source of supply and support, basic things that will be done, major associates, and types of expenses that will create more values, return on investment, job satisfaction and other intangible values.

Figure 5
Percentage of Non-conformances addressed annually:
2014-2019.



Measuring work results or outputs based on expected deliverables and responsibilities takes into consideration observing, quantifying, investigation, and assessment. It is mandatory for the laboratory to assess the usefulness and value of the quality management system. Performance management systems are commonly used in organizations as continual improvement schemes. However, sometimes discontentment by staff and process owners prevents these systems from being effective (Guerra-Lopez & Hutchinson, 2013). Quality internal Audits and Management Review Meetings are two key performance evaluation tools in ISO 9001:2015. Nonetheless, there is a possibility of great danger in “window-dressed adherence” where documented processes are adequately prepared while the activities are not implemented and objective evidence not seen. The establishment of quality culture entails regular implementation of very potent and effective ethics and codes of practice (Barata & Rupino da Cunha, 2015).

Figure 6
Number of Annual MRM Action Plans: 2014-2018



In an article by Hermi, Ben Romdhane, and Ketata (2009), three new approaches were proposed to evaluate and improve the QMS efficiency and effectiveness. In the first approach goals were identified and a schedule of work was designed to implement the goals. In the second approach a proficient and reliable scheme was developed considering all clauses in ISO 9001. The third approach emphasized information assessment and reviews to validate organizational pronouncement and enhance QMS. Together these three ideas will equip and help the management team pursue development programs and make deployment of quality management system easier. Quality management practice with an emphasis on ISO 9001 requirements and ideology often directs organizations into implementing narrow-minded and theoretical approaches in meeting customer needs, rather than thinking outside the box and identifying robust strategic programs to resolve challenges and improve productivity (Li, Zhao, Zhang, Chen, & Cao, 2018). Setting of objectives, continual improvement, as well as consistent enhanced productivity are elements of a healthy and functional organization. To accomplish this, the following should be carried out; create a right approach to change and behavior, set out plans and milestone, establish and implement applicable capacity building curriculum, and institute groups that will coordinate, identify and solve emerging problems (Nankana, A. 2005).

Figure 7
 Number of Implemented, Not Implemented and Partially Implemented MRM Action Plans: 2015-2019

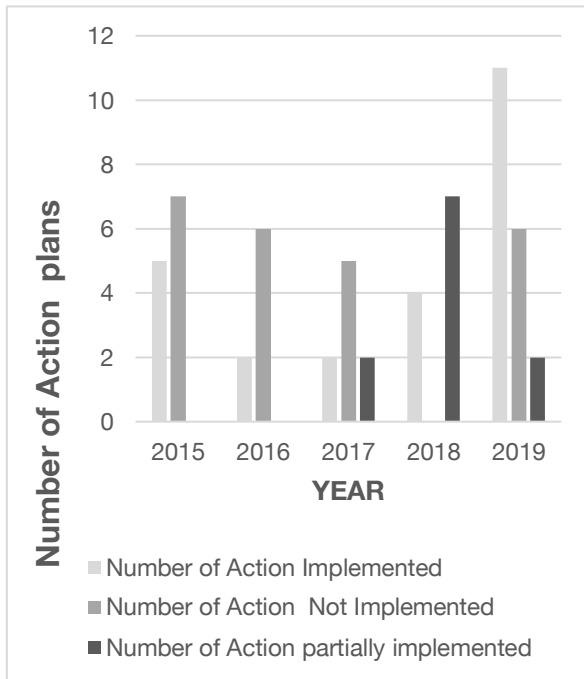
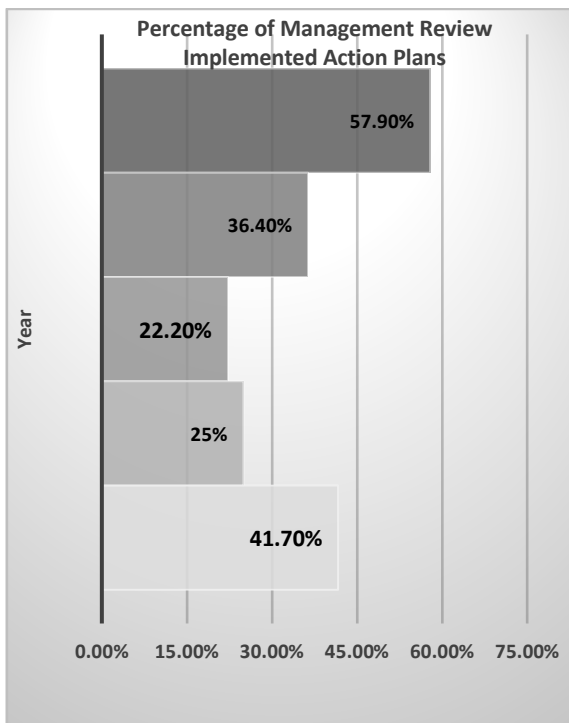


Figure 8
 Percentage of Management Review Meeting Action Plans implemented: 2015-2019



Conclusion

Quality Management systems supports organizations to guarantee accomplishments of set goals, develop competencies, and grow steadily (Wilson, Graham, Robertson, & Lennard, 2018). Like success, quality is not a destination, but a journey; it is not an act but a habit.

Resourceful, proficient, and consistent laboratory services and links are key for a service oriented, thriving, and appropriately designed health system (Gershy-Damet et al, 2010). Sustained and continual growth of the laboratory QMS ensures validity of test results, ensures customer satisfaction, and ultimately ensures patient safety.

The findings of this study have provided the laboratory with evidence-based data to make informed decisions and address possible causes of declining quality improvement. It will also help identify other opportunities for improvement and enablers of continuous improvement, that will complement the laboratory's current performance evaluation tools of internal audits and management review meetings.

From the findings it was concluded that, although the laboratory had implemented and established all components of QMS, there was absence of a quality culture. This can be seen in the identified gaps in improvement of laboratory QMS as presented in the inconsistent growth pattern of the QMS. It was observed that fulfilling standard requirements is not sufficient to establish and improve a system. Analysis of the data showed that consistent annual quality audits and management review meetings failed to improve the QMS as expected. There was increased reoccurrence of non-conformities despite improved knowledge. The laboratory can explore other enablers of continual improvement that are not documented in standard literatures employed in establishing laboratory QMS. These include building organizational quality culture, investing in human capital attitudinal and behavioral changes, establishing a reward system, improved remuneration, and developing a robust business plan for the laboratory to operate as a viable business venture. All of these enablers will empower the laboratory to consistently deliver accurate, reliable test results and improve access to quality assured medicines in West Africa.

Continual improvement is a fundamental and significant part of quality management. However, it involves adequate preparation, governance, dedication, responsible guidance, direction, constructive, and active involvement (World Health Organization, 2011).

Recommendations for Next Steps

The significance of learning, knowledge management, and creation of novel education in a learning organization is essential for continuous improvement (Asif, Searcy, Zutshi, Fischer, 2013). Recommendations for next steps include restructuring the laboratory training programme to include topics on leadership, relationship management, emotional intelligence, knowledge management, and others that will impact not just the Key Performance Indicators (KPI), but also the Key Behavioral Indicators (KBI).

A proper, correct, and standard quality management system should be designed to demonstrate a movement toward enhanced and value-added work ethics and principles, meet defined goals, correct and alleviate errors and potential threats, and achieve continuous improvement (Wilson, Graham, Robertson, & Lennard, 2018). When quality management observances are implemented, it takes a while before ethics, values and principles are modified. It essentially requires a long period for the organization's leadership and other workers to depart from the old ways, values and mode of operation, and then embrace the importance of total quality ideology (

011). Therefore, management should invest in long term re-education of themselves to produce appropriate traits then re-educate subordinates to produce appropriate attitude, positive behavior and good work ethics.

Another recommendation is that the laboratory takes extra steps in developing an organizational culture of quality by adapting and aligning quality and business strategy (Yu, 2016).

This will build a robust quality capability culture and imbibe the five capability building blocks to attain and sustain quality and compliance. The five capability building blocks are as follows:

- i. Organizational culture based on smart, healthy and continuous improvement learning organization;
- ii. Governance management controls-management oversight and controls, quality oversight, staffing, trend detection, redirect resources;
- iii. Employee engagement and organizational performance enablement - SOP compliance, training, quality culture, performance management
- iv. Quality systems robustness (in place and in use) - deviation process, laboratory control improvements;
- v. Fit for purpose-organizational simplification – facility, process, equipment technology investment and capacity.

Organizational culture based on smart, healthy and continuous improvement learning organization; Governance management controls-management oversight and controls, quality oversight, staffing, trend detection, redirect resources; Employee engagement and organizational performance enablement - SOP compliance, training, quality culture, performance management; Quality systems robustness (in place and in use) - deviation process, laboratory control improvements; Fit for purpose-organizational simplification –facility, process, equipment technology investment and capacity.

The laboratory can also embark on re-engineering of laboratory processes. This can be achieved by automating some processes using inexpensive technology and streamlining laboratory processes to eliminate duplication. Wastage is also reduced by proper needs assessment, inventory management, retraining laboratory managers on current management techniques and also developing a good cost-effective business plan for the laboratory. These re-engineering activities can save cost that may be channeled towards improving remuneration and staff motivation. Everything is evolving. An excellent performance today might be just the benchmark of tomorrow. For the laboratory to remain relevant and operate optimally, continual quality improvement is not negotiable and should be pursued relentlessly with all sincerity of purpose to ensure that hundreds of millions of people in the West African sub region have access to the right quality of medicines and their health is safeguarded.

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