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Implementation of an Electronic Quality Management System using Q-Pulse: The KEMRI-Wellcome Trust Research Laboratories Experience

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Abstract

Background: The KEMRI-Wellcome Trust Research Laboratory's expanded scope, its regulated environment coupled with the complexity of the laboratory processes and procedures to support diagnostic, clinical and basic research has made it difficult to manually manage its quality systems. We sought to automate the process to improve efficiency.

Objectives: To implement a centralised electronic quality system using Q-Pulse.

Methods: A concept note detailing the objectives of automating the laboratory QMS was developed. The implementation strategies employed included provision of technical support through installation, customization, training and data entry.

Results: The system was successfully implemented in May 2017. Out of the 30 workflows created, 8 were for document module, 5 each for audit and CAPA modules and 4 each for people, equipment and training modules. A total of 140 laboratory staff were trained.

Conclusion: The laboratory can now manage the huge documentation and there is reduced bureaucracy, increased efficiency and awareness.

Keywords: Quality management system; Q-Pulse; QMS automation; Good clinical laboratory practice; Electronic quality management system

Introduction

Managing a paper-based quality management system can be extremely difficult in regulated environments [1,2] and even further complicated in a large organization with many staff. Paper-based quality management systems used to be very common in medium-sized organizations and can successfully manage process quality. However, they significantly increase the risk of non-compliance to accreditation regulated organizations [3]. This has been one of the major drawbacks faced by organizations implementing paper-based quality management system. In this current era, it's no longer news that anything tagged 'electronic' is associated with efficiency and effectiveness, and that is exactly what is expected with an electronic quality management system.

The KEMRI-Wellcome Trust Research Laboratories has implemented a quality management system (QMS) in compliance to Good Clinical Laboratory Practice (GCLP) marked with a lot of documentation inform of records and documents to ensure compliance [4]. These documents and records generated by the processes must be controlled to reduce document-related non-conformances, provide up-to-date information and ensure only approved ones are available. Access and review of these records and documents is often limited, and time consuming, thus submission of quality assurance (QA) progress reports is always delayed. Furthermore, printing of these records and documents is costly, making compliance to the GCLP standards quite expensive. It based on this background that the KEMRI-Wellcome Trust Research Laboratories decided to implement an electronic quality management system using Q-Pulse with the aim of reducing the cost of printing while promoting awareness, access, efficiency and effective time management through timely reports which could have been lost by delayed submission of reports.

Objective

The main objective of implementing an electronic quality management system (QMS) was to enhance efficiency and effectiveness by reducing bureaucracy that comes with the paper-based QMS implementation, promoting awareness and access to QMS documents and increasing accountability. Q-Pulse compliance software developed by Ideagen company Ltd, was chosen to achieve this objective because it was easy

to customize and adapt to the compliance standards ascribed in it.

Methodology

A concept note detailing the strategic objectives of automating the laboratory QMS based on GCLP standards was developed. The concept note included the processes to be automated and in what sequence. This was reviewed by the information technology (IT) and procurement departments with a view to source for companies that would help the laboratory achieve this objective. The criteria for the evaluation of these companies as described in the project concept note were based on experience in implementing automated QMS in at least ten international organizations; ability to provide customized training courses and training courseware; must be in QMS automation business for the last 10 years; and able to provide local support whenever required. Based on the evaluation criteria, Q-Pulse application software developed by Ideagen company (UK) [5] was chosen because of its readiness to provide local support through its partner company, Intex Management Services [6] which is situated in Nairobi, Kenya.

An implementation model consisting of four main steps was then developed to automate the laboratory QMS system mainly installation, training, customization and data entry.

Installation

This involved installing the Q-Pulse application software to the existing information technology infrastructure system by the experts both from our IT department and Intex Management Systems company. It involved integration of the Q-Pulse components with the institution's servers by creating active directories, setting messaging system and coding on the server environment to enable easy access of the Q-Pulse application internally.

Customization

This was immediately after installation and mainly involved adapting the Q-Pulse application to the laboratory existing QMS. It required visionary thinking of the paper-based system into the Q-Pulse application system by defining the system's data that will appear in the drop-down lists. Through this, several workflows for document control and management, corrective action preventive action (CAPA), audits, training and equipment management framework were developed and tested. The entire customization process was completed within one week.

Training

Three levels of training were conducted to three different groups with the aim of ensuring successful implementation of the QMS automation. The first training level was done to Q-Pulse administrators who were mainly laboratory QA personnel and a technician from the information technology (IT) department. Q-Pulse administrators were charged with the responsibility of managing the system. The second level of training was conducted to Q-Pulse champions who were mainly laboratory personnel selected from each laboratory section; while the third training level was done to the entire laboratory personnel. The training programme for the three training levels varied with the roles and responsibilities assigned with regards to depth of usage of the Q-Pulse e-QMS.

Data entry

Once training was completed, the existing data in hard copies were scanned, history keyed in the system to capture historical data. This was done retrospectively from 2017 to 2015. It involved previous SOP versions, filled corrective action preventive actions (CAPA) forms, audit reports, training and competency documentation, and equipment documentation such as inventory, service records, calibration records and. This was done to operationalize the system.

Results

A total of 140 laboratory staff inclusive of 10 Q-pulse champions and 3 administrative Q-Pulse users were trained on Q-Pulse system (**Table 1**). The 3 Q-Pulse administrators were responsible for managing the Q-Pulse administration module, while the 10 Q-Pulse champions were to help in further training of laboratory personnel within the various laboratory sections. A total of 8 workflows were created to mimic the document/record development cycle, 5 audit workflows created, 4 equipment management workflows and 4 workflows each from people and training (**Table 2**). Several QMS documents were easily distributed to and accessible by laboratory staff thus reducing the bureaucracy which comes with the manual QMS implementation.

Table 1 Showing the category of Q-Pulse training, number of staff trained and their roles.

Training level	No. of staff trained	Role of staff within each level
Q-Pulse administrators	3	Designing the system, allowing access and other administrative duties. Master trainers
Q-Pulse champions	10	Equipped with detail knowledge to assist in training other Q-Pulse users
Q-Pulse Laboratory users	127	Learning and acquiring skills and knowledge of navigating Q-Pulse application system.
Source: Author's own developed		

Table 2 Q-Pulse modules implemented and their associated workflows.

Module	Number of workflows created
Document and Record Management	8
Corrective Action Preventive Action	5
Audit management	5
Equipment management	4
People management	4
Training management	4
Total	30
Source: Author's own developed	

Discussion

The advancement of technology has played a great role in this 21st century and has made implementation of quality management system easy under complex environments. The transition from the paper-based to the electronic system has enabled us to redefine our scope, govern the laboratory processes and activities, monitor the compliance while supporting change management and providing room for improvement.

Through the automation process, there has been reduced bureaucracy. This is because the laboratory Quality Assurance (QA) team no-longer needs to follow up staff physically to perform QMS actions as the system send notifications and reminders to them about their QMS actions. Staff interaction with the Q-Pulse system has led to increased involvement of staff participating in the QMS activities thus enhancing QMS knowledge levels. The automation of the QMS using Q-Pulse has promoted awareness of various QMS activities and tasks among the laboratory staff. Staff can now login to Q-Pulse system, perform QMS tasks anytime and access documents anytime. Moreover, the system sends notifications and reminders of various QMS actions. This has led to reduced bureaucracy and improved the operational efficiency [7].

The implementation of automated QMS was successful because of the backing of the laboratory management and staff involvement at all levels and concur with Frank's et al. [8] statement that management support and staff involvement is critical to the successful implementation of any QMS projects. The successful implementation of the QMS automation also agrees with a study conducted by Siloaho and Puhakainen [9] which found out that staff involvement is critical to the implementation of QMS. Involving the laboratory staff at each stage of the implementation made them empowered and enhanced ownership. The laboratory's management authority and commitment [10] coupled with the staff commitment and provision of resources such as desktop strategically placed within the laboratory where Q-Pulse application system could be installed and accessed led to increased staff awareness and knowledge of QMS.

Designing an effective training programme and conducting extensive training played a central role in the implementation and promoted QMS awareness, enhanced QMS knowledge and was a key tool to enhance improvement [11]. Conducting three levels of training to three different groups also led to the success of the implementation of the QMS automation process. Training of laboratory QA personnel and IT technician as Q-Pulse application administrators helped in the running of the entire system and offering administrative support. It is worth noting that the Q-Pulse administrators were static, but the other users were dynamic and always dependent on the scope of the task assigned. The Q-Pulse administrators had the responsibility of assigning new roles to responsible people and granting them permission to login to Q-Pulse and perform the assigned QMS tasks. Training of 10 laboratory staff as Q-Pulse champions who were mainly charged with the responsibility of training staff on Q-Pulse application system within their laboratory sections also led to the success of this project.

Through the automation of the laboratory QMS, there has been improvement in document control, CAPA, equipment management, training and competency and audits and this has helped the laboratory maintain its compliance and accreditation to GCLP standards as indicated in the GCLP certificate of accreditation as indicated in **Figure 1** below.


CERTIFICATE OF ACCREDITATION

Good Clinical Laboratory Practice

Name and address of Company Accredited

KEMRI Laboratories
Kilifi and Mtwapa
Kenya

Date of Accreditation
3rd May 2018

Category of Accreditation
Full Accreditation

Accreditation is continuous from the date of the previous accreditation on 1st December 2016

The above company has satisfactorily implemented the requirements set out in the Good Clinical Laboratory Practice (GCLP) standard, 2011, ISBN 978-1-904610-00-7

Date of Assessment: 2nd and 3rd May 2018

Re-assessment due date: Quarter 1/2 2019

Type of work accredited: Immunology, STAT laboratory, Microbiology, Serology, Virology, TB, BioBank, Molecular, Insectary and Safety Laboratories

Accreditation number: 01407

Laboratory first Accredited: December 2007

T R Stiles, Director
GCLP Accreditation Scheme

GCLP Accreditation Scheme operated by Qualogy 2002 Ltd www.qualogy.co.uk

Figure 1 Laboratory maintain and accreditation to GCLP standards as indicated in the GCLP certificate of accreditation.

Automating the document control and management processes by creating workflow-based document mechanism helped in assigning different roles and tasks within the document lifecycle to make sure the document is aligned with the corresponding processes [12,13] and further ensure that staff have access to current and up to date documents and eliminate document-related non-conformances [3] thus promoting a quality culture that enhances a continuous quality

improvement. The workflows created for audit, CAPA, equipment, people and training modules based on each module principles too led to the success of this project.

It is also imperative to note that the implementation was successful because of the integration of Q-Pulse into our existing IT infrastructure [14]. The success of automating any QMS system is dependent on having competent IT personnel as well as a concrete information technology system [15].

Since its inception in May 2017, we have managed to maintain our accreditation standards (**Figure 1**), and this has increased confidence as well as competence recognition by producing reliable data which agree with the literature from Holdsworth [3]. This implies that our laboratories are recognized for operational performance, quality management system and competence. Adherence to GCLP standards using Q-Pulse has decentralized the quality management system, thus improving operational efficiency [7].

Conclusion

This project aimed at implementing a centralized electronic quality management system in a laboratory that is accredited to Good Clinical Laboratory Standards. This was achieved and later unconditionally accredited by GCLP accreditation scheme operated by Qualogy Ltd (UK).

The implementation plan described here can be transferable to other organizations, as it is adaptable, and stress the importance of management commitment and staff involvement. Designing an effective training programme during QMS automation is equally useful in reducing the misunderstanding issues and increasing staff awareness.

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