Chapter

Total Quality Management in a Resource-Starved Nation

Martins Emeje, Kokonne Ekere, Olubunmi Olayemi, Christianah Isimi and Karniyus Gamaniel

Abstract

Total quality management (TQM) is defined as management approach, which empowers employees to adequately satisfy the customer needs. For efficient TQM, management is required to be fully committed, focused and goal-driven. The needs of employees such as tools and resources required for efficiency, self-improvement and corresponding recognition to reward for hard work are paramount in TQM; to achieve this in a resource starved nation such as Nigeria is a huge challenge. In 2016, the National Institute for Pharmaceutical Research and Development (NIPRD) decided that it was adopting TQM in its research and development activities. The challenge, however, was lack of infrastructure and trained personnel in this highly specialized and sensitive area. Respite came when the United States Agency for International Development (USAID) through the United States Pharmacopoeia Convention Promotion of Quality Medicines (USP/PQM) agreed to provide support. Two years later (2018), NIPRD laboratory has been accredited by the American National Accreditation Board (ANAB) as the only academic institution and probably the only academic-based research institute in West Africa. We discuss herein TQM in a resource starved nation like Nigeria and propose that developing countries should collaborate in all areas of TQM with a view to upgrading institutions to international standards.

Keywords: total quality management, ISO 17025, international aids, infrastructures, personnel motivation

1. Introduction

Organizations are set up to either fill a need, solve actual problems and/or satisfy the needs of their customers and very often, this is achieved through adherence to international standards epitomized by total quality management. The quality of the final product or services is assured only if quality was built into the product rather than waiting to check the quality of the outcome. Furthermore, human resources are vital in any laboratory quality management system. Therefore, it is expedient that the organization is able to effectively manage its human resources to bring about successful implementation of the total quality management system [1, 2].

Quality is an important aspect of delivering goods and/or services. It is a vital feature of any project that wishes to attract, retain and satisfy customers. Total quality management itself is defined as management approach which empowers employees to adequately satisfy the customer needs. These approaches include qualitative

techniques of organizing human resources in such ways that meet the present and future needs of customers. For efficient total quality management, the management is required to be fully committed, focused and goal-driven [2]. Total quality management ensures that products are not just handed to customers but that they are served with relevant information, and given apt responses to questions and needs through appropriate feedback systems. In addition, the needs of the employees such as tools and resources required for efficiency, self-improvement programs, and corresponding recognition to reward for hard work are paramount in total quality management; achieving total quality management in a developing country, especially, a resource-starved one like Nigeria is no mean task; the National Institute for Pharmaceutical Research and Development walk on this path of quality (ISO 17025) *via* total quality management was expectedly a tedious task, but, the support of the United States Agency for International Development (USAID) and the United States Pharmacopeia Convention and Promotion of Quality Medicines (USP/PQM) through training and provision of simple but basic materials helped us attain this feat; In 2015/2016, NIPRD decided it was adopting total quality management in its research and development activities. Two years later (June 2018), NIPRD laboratory has been accredited by the American National Accreditation Board (ANAB) as the only academic institution and probably the only academic based research in West Africa in ISO 17025. We discuss herein our personal experiences of trying to adopt and/or adapt international standards of total quality management in Nigeria, a resource starved nation. We conclude by proposing that developing countries should collaborate in all areas of total quality management with a view to upgrading institutions to international standards [1–4].

2. Documentation, work ethics and professionalism

The customer is always right! This is an adage that has been used as a business culture to guarantee that customers are satisfied. In this millennium, attention is placed on improving ways to achieve customer satisfaction through developing resources. However, without good management, these resources could degrade, break down or become inefficient which ultimately affects the outcome to customers. Nigeria is a country rich in natural resources; oil and gas, coal, limestone, ore and other agricultural resources which serve as innovative starting materials for various industries and the Nigerian Government has over the years established several policies and programs to harness and develop these resources through several means including research and development. The National Institute for Pharmaceutical Research and Development (NIPRD) was established with the mandate to employ research and development as a means to promote economic growth *via* development of indigenous resources [4, 5].

NIPRD is an academic based research institute with many intellectuals; a fertile ground for training students, intern pharmacists and professionals from various institutions around the globe. Our research entails development of methods and skills to fulfill a particular purpose and we do this from the stand point of intellectuality and with utmost care [6]. NIPRD's ISO 17025 certification was made possible with support from International agencies such as USAID and USP (PQM). They taught us several processes leading to the achievement of total quality management and we were guided by several quality systems; one of which is good documentation. Documentation itself is seen as the means by which systems/organizations strive to instill quality into processes and products. It portrays the goals towards achieving quality and cascades to all categories of the organization. Documentation is a correct, complete and concise practice that provides information to meet the customer's requirements, it also ensures that accurate observations are made with regards to the process and the product. It is important that all steps governing a

process be well-written down, reviewed and approved by appropriate authorities; more so, it is easier to remember what has been written down than what is said verbally. Therefore, documentation is a critical aspect of research that involves the supply and collection of information and ensures continuity of ideas. Quality management systems organize documentation into different levels like; policy, procedures, work instructions and records such that changes in any aspect of documentation would not affect other aspects [3].

2.1 Quality policy

This is the very first step in determining the path to total quality management; the policy written in the quality manual defines the organization's goals and principles, stating what is to be done and how to achieve it in simple and plain terms. This document becomes a legal tender for operations involving both the employees/staff and customers alike. The NIPRD quality policy is contained in the quality manual; developed to give information about the management structure and its lines of communication to all levels of staff. This policy also enumerates the role management plays as it relates to accountability and authorization in the Institute and its laboratory. NIPRD quality manual identifies the different scopes of activity and services that can be rendered and the timelines for delivery of results, in addition, the quality manual also contains the processes for feedback and response from customer satisfaction [1].

2.2 Procedure

This describes documentation of techniques and methods that are applicable in accomplishing all that is stated in the quality manual. It defines who is to handle a procedure, the specifics of that procedure or process, where and how this would be executed as well as all information useful for conducting an analysis or rendering service. Our ways of conducting business in NIPRD was refined with the advent of ISO 17025 and this has enabled us assure the quality of results given out to our customers. For example, ISO requires that each analyst have a populated file in the laboratory apart from his/her personnel file which is resident in the Institute's Department of Administration upon employment; this procedure was strange to us because the belief/thought was that since every staff was employed based on his/her expertise, there would not be need to have any of such other documentation that specifies his expertise in the laboratory. However, we learned this type of documentation which includes items like; curriculum vitae, job description relating to the specific analysis that he/she does and the equipment he/she can handle is very crucial to quality management. More so, such details as educational qualifications have also been adopted to be included in the analyst's personnel file; this shows proof of the ability and competence of the analyst to operate an equipment and carry out analysis.

Another scenario in the NIPRD laboratory is that of documentation in the "sample receipt logbooks". When samples are brought in for analysis, they are usually passed through the Business Unit of the institute (Consult Unit) where all the necessary information about the sample received and the analysis to be performed on the sample is documented. Such sample is then given a unique description (ID) in form of numbers or codes and sent to the laboratory for analysis as required. In the laboratory also, all information about this sample; the name, type or form of sample, manufacturing and expiry dates, NAFDAC registration number, the assigned ID etc. are recorded in the sample receipt logbook, showing evidence of receipt. However, for samples procured by individual researchers for research purposes, no entry in the Business Unit or in the laboratory sample receipt logbook was usually made. This is because we did not term such samples as "business samples" even though all

such information about the sample was usually written in the researcher's notebook. Conversely, ISO taught us that all samples to be received into the laboratory had to be received from a central point; the Business Unit and had to be documented. This new approach was difficult but, we welcomed and adjusted to it as an integral part of total quality management to ensure traceability and quality. This is also true for chemicals used in the laboratory; when requests are made to the NIPRD store, all receipt from the store is also entered into the appropriate receipt logbook with suitable information traceable to the suppliers, the store and the laboratory. All these form part of the controls that ensure quality is built into products given to customers [1–3]. Although NIPRD has in time past being offering trainings on various levels to its staff, we did not for once give certificates to participants, because, we thought such "in-house trainings" did not require certificates of participation. However, the walk towards ISO certification showed the necessity of such documentation and we adopted it; issuing and keeping all training attendances and certificates for training received and given. Even minute details like having a register for cleaning of the laboratory have been embraced as part of the process to achieve total quality.

Another culture of ours at NIPRD was for the Head of Laboratory to notify the responsible analyst(s) about any sample request upon its receipt. Then the analyst would report back on the availability and/or sufficiency of materials and equipment needed. Furthermore, in trying to ensure good quality and customer satisfaction, we learned that only analysis requested for should be conducted using appropriate methods as requested by the customer or stated by pharmacopeia standards and/or validated methods. On the other hand, when carrying out research and a method cannot be adopted, we usually substitute with another, but through the process of ISO certification, we realized that such change or substitution in methodology need to be communicated to the customer with adequate information on the reason for change and then an approval for such substitution must be obtained [3]. Even though it is expedient to adhere to stated methods, sometimes in carrying out research, innovations could occur or challenges met on the bench. This actually is what research is all about; where you discover a new thing, an unlikely outcome in the process which could become the heart of that research, leading to a patent! As is with every research in the developing world, adjustments are usually made to the quantities of materials and/or choice of medium or solvent used as a result of unavailability. This process of documentation does not only clarify the methodology to be used but assures that the customer is ultimately satisfied with the process of analysis.

2.3 Work instructions

These are detailed guidelines/directives stated in simple but concise terms on how to actualize the procedures presented above. We discovered that, for utmost effectiveness, such instructions are best written by the process owners i.e. those who would be responsible for carrying out the tasks. This helps to ensure that appropriate steps are taken in carrying out all tasks in addition to creating ownership and professional pride for those involved. These instructions could be; techniques or method of each procedure, the equipment to be used, how and when it should be maintained, the type of environment required for such procedure, the requirements for handling materials to be used and the safety measures for those involved in executing the process. In addition, references of other procedures relating to the analysis to be carried out, the factors to be considered in producing good outcome and the procedure to confirm that the outcome/products meet the requirements are also documented. These instructions are placed physically at the point of use so that they are visible to all. In the NIPRD laboratory, we have these instructions placed just by the equipment to be used so that the very first operation like turning or

switching on the equipment can be performed as required. We also have documents (Standard Operating Procedures; SOPs) drawn up for every procedure, these point out detailed step by step operation or instructions for each process. Even tasks as little as cleaning are not excluded in the documentation, we had "cleaning schedules" which stated the persons charged with keeping the laboratories cleaned. It is essential that every user understands and masters the requirements in these SOPs and that it should speak to the exact steps the user will need to perform. All users are expected to be knowledgeable and trained periodically on these SOPs, and even when proficient users are given other job descriptions, it is compulsory to have them trained on the operations of the new job.

2.4 Records/results

These are the outcome of whatever task or analysis that was performed. They could be given as forms which have been stamped and/or signed showing approval of the process, outcome or product. Other records could be the supplier's documents, records of equipment calibration and maintenance and in addition results of audits conducted. This makes all actions traceable and provides data for correction where necessary. Appropriate documentation of results would also show how the product was verified to have met specifications and the customer's expectation. Part of attaining good quality systems entail that records or results are filled correctly and at the time the process was performed; with pictorials where necessary. In principle, what is not documented was not done! Record keeping or data management is a crucial aspect of ensuring quality in any organization and so must be taken seriously. Data must be stored appropriately and be accessible or retrievable when needed and where new records exist, the old should be kept for a specified period before being discarded. It is important that testing laboratories provide proof that the processes used met defined objectives as stated in their policies and it is the prerogative of each laboratory to define the records and results necessary to achieve this. In the NIPRD laboratory, the proof of following processes or procedure are the data or results generated during the process; these are usually in form of print outs, results from investigations and requisitions or memos. Our filing systems basically include the use of laboratory note books and computers; these are properly signed by the analysts who conducted the analysis and then verified by technical managers. Data stored in the computers are secured by passwords which are only accessible to the analyst (who entered the data), the technical manager (who verified the data) and the Head of Laboratory (who reviewed the process and the results). All the procedures leading to appropriate data storage are succinctly documented in the appropriate SOPs. At the end of every analysis, NIPRD laboratory issues a Certificate of analysis to the customer through the Business unit stating the results of the analysis. Records/results could also include investigations into reasons why processes failed (non-conformance), who or what was responsible for such failure and the corrective/preventive action (CAPA) plans to forestall such occurrences. Other records include calibration reports, reports of internal/external audits and equipment maintenance records. The TQM ensures that documentation defines the series of processing, standards and techniques required to preserve the quality of a system through monitoring and continual improvement to the end in order to ensure that the customer's needs are met [3].

2.5 Work ethics and professionalism

Ethics begat quality and one cannot exist without the other. For an organization to deliver on quality, it must be guided by such behaviors that lead to right-doing. Some

individuals learn these ethics as part of their life-long growth process while others acquire it on the job through training. This means our cultural background and level of exposure play an important part in deciding what is wrong or right and what a wrong or right process is. Therefore, it is quite essential that an organization sets its own code of ethics as a means of control, however, these must not be high-ended but achievable. Good work ethics and professionalism are part of the measures required to attain total quality management. It is actually not sufficient to just set the codes/rules but to provide resources that support these codes. Therefore, management must be committed to ensuring staff have the prerequisites for realizing its goals/policies and this can be attained through training. Training and re-training is an integral part of total quality management and we went through diverse forms of training by USP trainers. The records of these trainings show the competence of each persons involved in the process of analysis and guarantees that he/she has the minimum required to perform such process and in order to build quality into the product [7, 8].

NIPRD, being an academic institution, prides itself in academic growth and excellence, we develop our career through ascension in the academic ladder by undergoing higher degrees, relevant trainings etc. [6]. Total quality management requires that each staff has the requisite knowledge in doing their assigned jobs, carrying out analysis *via* exposure to current techniques and instrumentation necessary for the analysis. All analysis must be conducted with utmost professionalism while also ensuring customer satisfaction. In order to build a strong team, the management must ensure that staff performance is measured and assessed; staff evaluation and recognition is a critical aspect of total quality management which has been the culture in NIPRD. Periodically, staff in NIPRD assess their colleagues and the reward or otherwise is solely a result of that assessment. This gives rise to healthy competition which helps to build a team of competent and goal-driven employees. Although NIPRD is an institution with many departments and units, we have learnt to break down barriers of work space and embrace the concept of working across units. This has led to wholesome and total quality of all evaluations/analysis and also improved customer satisfaction.

In addition to ensuring staff are properly trained, the institute also ensures that the appropriate equipment for each analysis is provided. All equipment are listed in a database resident with the Maintenance Unit and contains the calibration certificates of each equipment, the next due date for calibration, out of specification status (when the equipment has failed to meet the required specifications) and personnel authorized to operate the equipment. All these are geared towards keeping the equipment operational so as to achieve good results. Tropical regions like Nigeria are plagued with high temperature which could affect the process of analysis and ultimately the result. Therefore, monitoring the temperature of the environment becomes very important; simple tools like the thermo-hygrometer which were needed to for this were graciously provided by the sponsors (USAID/USP) and installed in the laboratory. Records from this device are charted to ensure that the temperature of the laboratory is controlled and suitable for both the equipment and the process of analysis; it became apparent that our work culture and attitude had to change once we saw that this was geared towards improving the quality of the system; it was no longer sufficient to just view results as they come but to critically analyze them. For example, the ISO requirement is that a negative result be investigated and not just thrown aside, this we learnt and adopted. Such tools as corrective and preventive actions are raised to make sure that the action is corrected and to forestall its future occurrence. In addition, staff are taught to investigate such results with questions like; why did this result fail to meet specification? How did it fail? At what point during the analysis do you think the sample failed? And who/what was specifically responsible for the said action? It is no longer enough to just identify the problem and move to provide solutions, it is good practice to

thoroughly investigate so that such actions do not recur in future. Ethics and codes are principles which bother on individualism and affects the manner in which each staff responds to these codes. People would usually subscribe to values or beliefs that they are used to and this expresses itself in the way they set out to achieve set goals and policies. It is therefore necessary for management to understand each individual's eccentricity and use it to achieve its goals but this does not preclude the necessary requirements of each employee in fulfilling his or her role in an organization moving towards achieving quality. Integrity, reliability, consistency, good communication, respect for other people's opinion and the sense of responsibility are important ethical codes/values that lead to quality [8–10].

3. Human resources in total quality management

3.1 The importance of human resources in total quality management

Human resources (HR) are a vital part of the quality management system and is one part that cannot go unrecognized. They are the sole most vital asset in any laboratory and they are led by a competent and accountable management whose main responsibility is to ensure the successful implementation of the total quality management. This aspect of total quality management is very critical because its quality determines the productivity of the laboratory and quality of all jobs performed. Without human resources there will be no quality management system. From the start to finish of a laboratory quality system the personnel involved go a long way in ensuring that this is achieved. The human resources comprise of the management team, quality assurance team/unit, analysts, security personnel, cleaners, etc. Each of these group of human resources is essential in the whole process as one cannot function without the other. They each have their contribution and unique role that makes total quality management a reality. For this to occur, team work is very important between the various groups of personnel. Team work between the management, analysts, and support services played a major role towards the success of the accreditation exercise. If this cooperation was not evident the quality management system would have been deficient. In the NIPRD scenario, the analysts were grouped together with a key person appointed as the lead. This was done to build a culture of team work between the personnel. The quality management system (QMS) is a system of interaction, which exists at all levels, i.e. between the management team, quality assurance team, analysts and others. It is this interaction that makes total quality management what it is and makes it successfully implemented in laboratories. Another unique feature of total quality management is that each group of personnel have a range of qualifications and training which is then harnessed together to form a strong team for the execution of the quality management system. Suffice it to say that human resource is the foundation on which total quality management is built [11, 12].

3.2 Function of human resource in total quality management

All personnel involved in the quality management system have specific roles and functions they perform. One of the requirements of the ISO 17025 accreditation is for all personnel in the organogram to have a file and this file contains the job description of each person. The job description entails a brief credential of the personnel, job summary, key areas of responsibilities in ISO 17025, research functions (level of effort), key working relationships, qualifications and experience, on-the-job training, key abilities and personal abilities. The leadership of the laboratory quality management system must have a set vision and goals for the

laboratory which they must ensure its successful implementation. They should have the necessary skills for team building, communication, motivation and resource management. The managerial and technical personnel all perform unique roles. The managerial personnel are shouldered with the responsibility of ensuring all resources needed are provided in terms of infrastructure, human, etc. The technical managers, deputy technical managers and analysts each have unique roles and functions they play. For instance, in the case of NIPRD, these are the various personnel involved in quality management system. Firstly, the Director-General is the contact person/coordinator of quality management system which all the other personnel report to. He/she is responsible for providing resources needed for the successful implementation of the laboratory quality management system. Generally speaking the DG/CEO is also the head of the laboratory because he/she coordinates, manages, and monitors all activities of the laboratory. Consequently, the management review meetings which are to be held regularly are to be chaired by the DG/CEO. In addition, the annual work plan and budget are to be reviewed and approved by the DG/CEO. He/she is also to ensure that the training plan for the laboratory is effectively implemented. Administrative duties and functions are performed by the Director of Administration and Supplies. These administrative duties include personnel appointment, welfare and laboratory store. The quality assurance unit made up of a quality assurance manager and two deputy quality assurance managers. This unit is the major driver of the quality management system because they develop the quality manual which guides and governs the activities of the laboratory. The quality manager is to ensure the correct application of the management system in the laboratory. They manage and maintain the laboratory quality management system and report directly to the Director General. All standard operating procedures generated by the technical scopes are to be approved by the QAU before trainings and implementation. They also schedule internal audits yearly and ensure that the appropriate corrective action plans are implemented. They can also be involved in any other activity as directed by the DG/CEO. The deputy quality assurance managers assist the quality assurance manager to achieve the set goals. They are also required to stand in for the quality assurance manager in time of absence. The deputy in charge of documentation handles all activities related to QA documentations and archiving. The quality assurance team is composed of the quality assurance unit and representatives of the various departments in charge of quality management system. The technical departments in NIPRD each have a head of department (HoD) who are in charge of the general supervision of all activities in the department. The HoD is the first port of call for receipt of samples from the consultancy services unit and is required to ensure the implementation of requirements in the lab quality manual. The HoDs report to the Director General. For each technical scope, a technical manager and deputy technical manager is appointed whose main responsibility is to ensure continuous availability of resources required for efficient and effective analytical testing in each test scope. In addition, they are saddled with the responsibility of ensuring the continuous monitoring of all laboratory operations. The technical manager/deputy technical manager allocates the samples for analysis. They also develop and ensure implementation of an annual work and training plan for the laboratory. All SOPs prepared by the responsible analysts have to be reviewed by the Technical manager before approval by the quality assurance unit. The competence of analysts to perform certain tests is essential therefore the TM develops competence tests for each analyst which each analyst must successfully complete before authorization. The equipment used by the analysts have to be properly maintained by the instrument maintenance unit therefore it is the responsibility of the technical manager to ensure that appropriate maintenance is done regularly. The technical manager reports to the HoD or DG/

CEO. The laboratory top management communicates with the subordinates through memos, management review meetings and Quality Assurance team meetings. The analysts are the key personnel involved in the operations of quality management system. All personnel are expected to sign an impartiality and confidentiality declaration form stating their commitment to the laboratory. Anyone found involved in dishonest activities would be subjected to the laboratories disciplinary action. They perform tasks by following laid down instructions and procedures and document their results in a specific manner. They report to the technical manager who reviews each work done in the laboratory notebook. The key analyst is in-charge of the technical operations of the equipment while the other analysts act as a support in case of absence. Apart from analysis of samples, analysts are responsible for preparing sample and standard, monthly reports, SOPs and other Quality Assurance documents. When errors occur during analysis, the analyst is expected to report same to the technical manager immediately. Hygiene and safety of the laboratory is very important therefore the analyst is expected to follow safety instructions and maintain the laboratory in a neat and clean manner. They also prepare standard operating procedures for each test scope which is then reviewed by the technical manager and HoD before seeking approval by the quality assurance unit. Before analysts can operate equipment within their test scope, they are expected to receive an authorization letter from the head of department after satisfactory performance on the competency tests. In addition, all laboratory personnel are expected to sign a confidentiality declaration form. The NIPRD consultancy services is also a part of the quality system; it is through this unit that samples are received and stored before allocation to the laboratory and these processes are all documented. They also receive feedback from customers concerning the services rendered so as to know areas that require improvement. In the event of a complaint from a customer, the consultancy services unit is expected to report same to the laboratory which will then investigate and implement corrective actions. The store unit is responsible for keeping of items required by the laboratory in the form of reagents or materials. The instrument maintenance team is a key component of total quality management; they deal with the maintenance of equipment used to perform laboratory tasks. Support services such as the security and cleaning personnel are also critical as the cleanliness and safety of the laboratory is essential. The results obtained from laboratory can be affected if necessary hygiene measures are not put in place [9].

3.3 Qualifications/experience of human resource in total quality management

It is important that all technical personnel involved in total quality management are qualified and experienced in order to perform their various tasks efficiently [3]. The quality assurance manager who drives the whole process should be someone with adequate knowledge and experience in quality management system. For example, in NIPRD quality management system the technical managers responsible for supervision of the technical activities are all highly qualified educationally and professionally, this includes professors and PhD holders. This is due to the supervisory role they perform; therefore, they need to be better equipped and have a thorough understanding of the technical activity so that they can correct or solve any difficulties the analysts may have. Apart from educational qualifications, there may also be some professional qualifications in laboratory quality management system that could also be beneficial. It is important that a personnel file is maintained which contains the curriculum vitae and all certificates to show the educational and professional qualifications of each personnel. The curriculum vitae of each personnel should contain their career objective and educational achievements. This is an essential requirement of ISO 17025 laboratory accreditation. In certain technical

areas the personnel are expected to have some certification. In carrying out some specific tests they are expected to have relevant knowledge of the technology used, required legislation and standards and understand the significance of deviations when they occur during the process.

3.4 Training of HR in TQM, the NIPRD model

Training and retraining of personnel is very essential in total quality management if they are to accomplish the set goals [3]. It is important for human resource to be kept abreast of recent developments in the area of total quality management. All personnel in total quality management need to be trained (technical and non-technical personnel). If training/retraining is not conducted, there is the possibility of knowledge gaps which will eventually obstruct total quality management. One of the management's commitments to the NIPRD quality management system as stated in the quality manual is to enhance the technical capacity of personnel in NIPRD laboratory through trainings. Peradventure the laboratory needs contract staff and additional support personnel, it is recommended that such personnel too are competent, trained and supervised in their respective areas. In the case of NIPRD quality management system various training programs are planned, approved by the management and documented. The initial training is a general orientation organized by the NIPRD administration for all new employees to acquaint them with the aims and objectives of the institute. Laboratory orientation is also done by the head of department for all laboratory staff including trainees. Continuous trainings which is done in-house and external trainings are all part of the process to add, change or reflect knowledge and attitudes. In preparation towards the ISO 17025 accreditation several trainings were conducted by consultants from USP/PQM and these trainings were highly rigorous. It included theory and practical sessions. The trainings were conducted at different levels with some involving only technical personnel while others involved all the personnel. The trainings which started in 2016 were highly structured and in most cases lasted for weeks. The external trainings in 2016 were basically to familiarize personnel with the ISO 17025 standards and guidelines to keep them abreast of what is expected of them. In 2017, a gap assessment program was conducted to assess the "baseline" state of the institute. The first part of the gap assessment was to review the status of the quality manual which is an important documentation. Also, sections 4 and 5 of the ISO 17025 standards was assessed. The second part involved a laboratory inspection which involved the sample receipt area. Practical demonstrations of the various technical scopes were performed. At the end of the gap assessment all deficiencies and opportunities for improvement found during the gap assessment were discussed. Practical trainings which included case studies and subsequent laboratory hands-on were conducted. Training on compendia techniques on the various technical scopes were conducted to make personnel aware of current pharmacopeia standards for each analytical test, this is because the ISO 17025 standards require that only current pharmacopeia methods are used for each test. Another feature of these trainings were the self-assessment tests which were often done before and after each training. These assessments were very interesting as they helped to give an idea of each personnel's state of knowledge in particular areas. Most times these trainings tend to cover all sections of the ISO 17025 standards. In NIPRD, personnel were trained on various aspects such as writing and implementing effective standard operating procedures, good documentation practices, root cause analysis, corrective and preventive action, internal auditing, handling out-of-specification (OOS) test results, etc. The trainings were highly interactive with times for discussions and contributions. They were highly educative as most personnel always learnt one or two new things at each session. In order to

check if these trainings were effective and being implemented by the NIPRD personnel, the USP/PQM consultants conducted external audit of the laboratory QMS at regular intervals to keep staff up to date. After each audit session, a report was done and corrective/preventive action taken. At the end of each training, certificates were presented to staff who performed well in the assessments. Completion of the training attendance form at each training session was mandatory as it was used as an objective evidence for earning certificates. Training evaluation form was used at the end of each training to assess personnel. Personnel training needs assessment form allows personnel to identify proposed training with dates for the year, location of training, description of training need, training duration and trainer. A training record form is to be kept in each personnel file and this contains a list of all trainings undertaken with location and date. According to the ISO 17025 standards, training is important because, before personnel can be authorized to handle an equipment, they must have gone through some competency tests at different levels to test their ability to produce reliable, reproducible and repeatable results.

3.5 Problems with human resource that could arise in total quality management

The importance of human resource in total quality management has already been extensively discussed. Suffice to say that, it is necessary that highly competent and trained personnel are involved in the NIPRD total quality management [2]. However, it is possible that unforeseen circumstances may arise with human resource which may affect the total quality management. Each laboratory should have an efficient method of dealing with such issues as may arise with personnel, so that it does not negatively affect the system. When human resources are not appropriately managed, this can affect the output of the organization. For instance, if personnel are not adequately trained to perform their given tasks, it can lead to fatal errors which may lead to death depending on the tests being performed. This is why training and retraining is a key component of human resource management in any laboratory. In addition, the reward system in each laboratory should be well established to motivate personnel. It is a known fact that if personnel are not motivated there would not have the zeal to perform work and this can also introduce errors in results. Therefore, it is essential that the welfare of personnel is taken seriously to improve their productivity and output. In the NIPRD quality management system model for example, three or four analysts were appointed, trained and authorized for each scope, this is to overcome any challenges that may arise due to absence of an analyst. In the ISO 17025 accreditation process of NIPRD, it was compulsory that at least two analysts be present for each activity at any point in time. No analyst was left alone to carry out tasks in order to avoid any issue of monopoly. This goes back to the subject of team work which brings about success because with team work there is no looser. We strongly believe that not monopolizing knowledge and involving everyone as a team was one of the factors that helped NIPRD. Though there were some attitudinal challenges with some analysts, this did not affect the smooth running of the whole process as there were always trained and competent personnel available.

4. Management in total quality management leadership

4.1 Leadership

The role of leadership in total quality management cannot be over emphasized [11]. Top management Commitment and leadership is a critical factor to the success

of total quality management implementation. Though there are many definitions given to leadership, we prefer to define leadership here, as the ability to inspire followers to share in, and work with the leader to actualize organizational vision. This is the definition that best fits the leadership that bought total quality management into being at NIPRD. The vision to making NIPRD a center of excellence for total quality management started way back in 2010 with the introduction of ISO 9001-2008 quality management system standards. Being a Research institute, the introduction of quality way of doing thing was a difficult task for the leadership as many were not aware of QMS and those who were, did not see the need for quality management system in a research institute. Because it was a priority for the leadership then, conscious effect was made to ensure the engagement of a consultant to lead the organization to being certified. The Institute got ISO 9001-2008 certified in 2015 but still struggles with the funds needed to maintain the certification. It is clear that, lack of sustainability plan is a drawback. NIPRD is a departmental based organization and the different scopes are domiciled in deferent departments unlike a company setting where all activities are centrally controlled under one unit. Based on the facility tour of the team, scopes where selected to be part of the total quality management. Once these scopes were identified, a meeting was held with Top and Unit managers with the aim to generate the gaps in training and infrastructural needs of every scope [6].

As a first step to ensure leadership commitment and participation, the management set up of a Quality Assurance Team who were to be responsible for the coordination of all activities that would lead to total quality management implementation. This team comprised of the Quality Manager, two Deputies on the first level and a representative from all departments/units on the total quality management program of the institute on the second level. The Quality Manager had the responsibility of being the liaison officer between the institute and USP/PQM representative. To ensure that leadership participation and commitment is maintained, management members were requested to be part of every meeting and training. The ISO 17025 model for total quality management implementation has different levels of leadership and all levels have to be responsible and committed to ensure implementation. NIPRD though running a traditional organizational structure that could support the quality management system of 9001 had to create another structure to support the total quality management. In this structure every level of leadership comes with different responsibilities and the success to implementation is dependent of all succeeding.

4.2 NIPRD organogram

NIPRD runs a normal traditional mechanistic institutional management structures which is characterized with a small upper management that make all the decisions. The management that makes all the decisions are DG and Heads of Department [6]. This type of structure management operates a top to bottom hierarchical management. This type of management is not supportive of total quality management implementation as employees tend to strive to pursue personal rather than organizational goals. The NIPRD Organizational structure which had a single line of communication had to be modified to one that has a larger authority and employees work more for organizational goals.

4.2.1 The DG/CEO

He is the overall head of the total quality management team and is saddled with the duty of creating an enabling environment for the successful implementation

of the system. Our experience shows that, the commitment and vision of the DG/CEO was a crucial element in implementing total quality management. Development of the vision statement which is one of the responsibilities of the leadership was done with the employees to ensure staff buy-in. The leadership is responsible for providing organizational framework needed to support the system. The education and continuous development of staff is one of the leader's responsibilities and this was adequately demonstrated by making available, the available resources to training all employees. At NIPRD, like many academic based institutions, departmental barriers exist and very often are obstacles to speedy execution of services. A successful total quality management must break this barrier, and this was achieved with the commitment of both the institute leaders and laboratory managers.

4.2.2 The quality assurance unit

The unit is directly responsible to the DG/CEO and they are in charge of the general implementation of the total quality management. They are responsible for the planning of and coordinating the various training needs of everyone. The Quality Assurance Team, which is made up of the quality assurance unit and the representative from all the departments involved in the total quality management was formed to be a support to the all processes of the total quality management system.

4.2.3 Head of department (HoD)

The second level of leadership under the total quality management organizational structure are the Heads of Departments and together with the Director General they form the Management. The HoD is responsible to the CEO and have all the responsibilities of management. All reports are passed through them to the quality assurance manager. Some of them also function as technical managers on scopes domiciled in their department.

4.2.4 Technical managers

The technical manager of any scope must be familiar with methods and procedures of the scope, he/she must understand the purpose of each test. The technical manager should be vast in in knowledge and well trained in the scope area and there should possess a training records to back his/her competency. The technical manager takes responsibility for the performance of the analyst by ensuring compliance with the ISO 17025. The TM ensures that the analyst follows all standard operating procedure and takes responsibility for any report generated from the test results. The technical manager has total controls on all technical operations and approves results for onward submission to the HoD before submission to the quality assurance manager.

4.2.5 Analysts

These are the process owners and need to have complete knowledge of the processes that they work with as this is critical to the success of the total quality management implementation strategies. Without knowing how to do the job, the analyst will not be able to improve on the process towards improvement. The knowledge of the process is achieved by repeatedly working with that process, and also continuous training. The analyst must be qualified and have training records to back their competencies.

4.2.6 Instrument maintenance unit

The maintenance unit on the NIPRD organizational structure is answerable only to the Director of Administration and all members in that unit belong to the department. This was however modified on the ISO 17035 organogram. The maintenance team was deliberately created to have representation from different department also done in a bid to break down departmental barrier and foster inter-departmental cooperation. The unit was created to manage all equipment in the laboratory, consequently named Internal Maintenance Unit.

5. Physical infrastructure as a challenge to total quality management

One of the major challenges when implementing total quality management in an organization in a resource starved nation like Nigeria is lack of basic infrastructure. Infrastructure could be physical or human. Physical infrastructure includes; environment, material, machine and money.

5.1 Environmental/cultural background

Culture is a series of laydown assumptions that a group of people has developed in learning to cope with problems of external adaptation and internal integration; they have worked well enough to be valid, and are therefore thought to new members as the correct way to perceive, think and feel in relation to these problems. It is hard to analyze an organizational culture because as an outsider, you will only understand how organization behave but rarely can one understand why it behaves the way it does. Cultural values of an institution such as company philosophy, norms and justification are communicative and people of the organization are aware of these.

The National Institute for Pharmaceutical Research and Development is made up of the Director General/Chief Executive Officer, highly intellectual research scientist of diverse field and specialization, Technologist and Administrative staff. NIPRD combines research and administration. Its vision is to build a Centre of Excellent in research and development of phytomedicines, pharmaceutical and biological products, drugs and diagnostics towards improving the health and well-being of mankind. It is therefore made up of 5 core departments [6] namely, Pharmaceutical Technology and Raw Materials Development, Medicinal Chemistry and Quality Control, Medicinal Plant Research and Traditional Medicine, Pharmacology and Toxicology, Microbiology and Biotechnology. However, achieving a uniform environment condition which is very important for total quality management and ISO is usually difficult due to the diversity of activities going on simultaneously in various laboratories. Bring the various departments in one roof where such condition can be achieved was difficult nut to crack for NIPRD due to its cultural background. Before total quality management can work, it is important to understand existing cultural values of the organization. Occupational background can affect the culture of an organization. Relationship between organizational culture and operational management have been established, people's belief influences existing practices and manufacturing performance. For long, underlying value systems influence how people behave and act. Knowledge of the environmental impact of a product, services or process is an important factor in eliminating the harmful parts in a product or service with respect to the environmental health of the society.

5.2 Cost of implementing total quality management

The cost of building quality into any product is capital intensive process at the initial stage, but may be cheaper and yield better result than testing for quality in a product, because, it reduces deviations and costly investigations, and also avoid regulation compliance problems. Money invested by an institution to minimize defect or prevent mistakes is believed to cost the organization little compared to the disastrous expenses that might be incurred by an organization if total quality management is ignored.

5.3 Tools for employee to use

The NIPRD is a parastatal of Federal Republic of Nigeria, and Nigeria being an oil rich nation, ordinarily should not have problems with funding of its public institutions, but this is far from being the case; most of the equipment NIPRD were certified for by ANAB were donated to the institute by USAID, in fact during the pre-assessment audit, the auditors made fun of the institute dissolution test apparatus as been too old and should be transferred to museum. The state of the apparatus was so pathetic that almost all components were not performing efficiently; for example, like all other equipment such as the pH meter, analytical balances, UV–vis spectrophotometers, etc., it had not been calibrated for decades. In such a situation, despite the willingness of staff members to adopt total quality management, it was difficult.

5.4 Epileptic power supply

With the meager resources allocated to the NIPRD, the institute run on generators for at least 6 hours for every working day [13]. A researcher will have to plan his/her experiment within this time frame. This makes it difficult to achieve optimum environmental condition since most reference samples and room temperature must meet international specifications. Most equipment needs chilled environment for it to function appropriately. Some equipment needs re-calibration once power supply is disrupted, in a resource starve institute like NIPRD, recalibration of some equipment up to 10 times in a day is possible, this will not only affect output as it is time consuming, it is also expensive. The state of the environment affects the output of staff. If it is harsh, workers will not find it conducive to give their best. A harsh condition affects the general output of any study. A functional environment can only be achieved where power supply is relatively constant/steady. To achieve this, a scientific approach to power rationing was developed [13].

5.5 Training of employee

Empowerment of employees is a common concept in virtually all organizations. Such empowerment leads to effective, innovative and transformation needed in enhancing global market with burst changes in technology. One of the ways employees can be empowered is by training and re-training. Managers can empower employees through information sharing, provide structure to the organization, train people and canvass for team work instead of hierarchy; as this will raise the level of trust from the employee and create a sense of ownership. Training should be a continuous process, focused, planned and customized to suit a particular organization. In establishing total quality management at NIPRD, our training effort was aimed at an integrated approach to the instruction process. Training enables the employees to carry out his/

her current task with much smoothness and ease, increase capacity, knowledge and the competence to do work efficiently while saving extra time and resources. Our 24 months experience on this journey clearly shows that, to attain a state of total quality management, training of employees should not be taken likely; during the ISO 17025:2005 exercise in NIPRD, members of staff were trained and re-trained theoretically and practically on various scopes by the USP-PQM/USAID. This has not only empowered NIPRD employees but also developed them physically and mentally, enabling them to carry out any related task effectively and efficiently. Aside been ISO 17025 certified, this training has enabled NIPRD attain a state of total quality management. Training and re-training is a form of reward and recognition of the employee. It makes the employee feel meaningful and satisfied because he/she is being appreciated. Loss of brain and intelligence would be reduced. This will help the organization carry out proper succession planning to fill the important post within the company instead of hiring new employee and training them on each and every aspect of the organization [14, 15].

5.6 Control of the monitoring and measuring resources

Calibration is comparing the readings between a measuring instrument or system to an applicable unit of some defined system of measurement. It is an age long process. Calibration is done using a documented, validated and controlled method for making the comparison. Calibration and re-calibration are very essential for any equipment to function properly. It is a way of maintaining equipment. It is repeated at regular intervals to give progressive assurance that the functionality of the instrument is suitable for use. A calibrated procedure indicates a need for adjustment or repair, and always repeated to verify the proper measurement relationship. In a resource starved country like Nigeria, it is a very expensive process because only few organizations are internationally certified to conduct calibration of equipment. All calibrated equipment should be traceable to SI unit. A validated and reproducible result will only be achieved with equipment that its calibration is up to date. The totality of total quality management is customer satisfaction and faulty equipment cannot produce a result that will satisfy a customer. The NIPRD ISO 17025 organogram has an Internal Maintenance Unit that were trained by PQM with funding from USAID on equipment maintenance and calibration, this has helped NIPRD to be ISO certified and also attain a state of total quality management. Importantly, reference must always be made to tests and verification of any observed or recorded error(s) in Calibration certificates and test reports, this is because, a calibration or test without the verification of the error is absolutely useless.

6. Conclusions

Every organization is set up to fill a need, solve actual problems and satisfy the needs of their customers. Our walk to this path of quality *via* total quality management was a tedious task but the support of the USAID/USP/PQM through training and provision of infrastructure has helped us attain this feat. The experience gathered from this project shows that, unlike developed countries, developing country laboratories may do well to collaborate in all areas of total quality management with a view to upgrading their institutions to international standards. In this respect, many laboratories could form cocktails towards accreditation in such a way that, each laboratory could be accredited in specific scopes instead of one laboratory struggling to have accreditation in more than one or more scope.

Acknowledgements

The authors are grateful to Mr. Adebola Adekoya of PQM/USP and other staff of USP, USAID, as well as NIPRD QAU and entire membership of the 17025 team for their technical and/or administrative support in the course of this project. The contribution of the dissolution analyst, Pharm. Isaac Ajeh, who graciously shared his experience with us in the form of written notes is also acknowledged.

Conflict of interest

No conflict of interest declared.

Author details

Martins Emeje*, Kokonne Ekere, Olubunmi Olayemi, Christianah Isimi and Karniyus Gamaniel
National Institute for Pharmaceutical Research and Development (NIPRD), ISO 17025 Laboratory, Abuja, Nigeria

*Address all correspondence to: martinsemeje@yahoo.com

References

[1] National Institute for Pharmaceutical Research and Development Quality Manual: (Based on ISO/IEC 17025:2005). NIPRD-QM-01-01. 2018. pp. 1-52

[2] National Institute for Pharmaceutical Research and Development Organogram: (Based on ISO/IEC 17025:2005). NIPRD-QM-OF-1-01. 2018. pp. 1

[3] International Standards General requirements for the competence testing and calibration laboratories. (ISO/IEC 17025: 2005). 2005. pp. 1-36

[4] Gilerman GL. Closing the management competence gap. Human Resources for Health. 2003;**1**(7):1-3. Available from: http://www.human-resources-health.com/content/1/1/7

[5] Jack JT, Nkwocha IB, Odubo T. Natural resource exploitation and socioeconomic development in Nigeria (1981-2015). Sustainable Human Development Review. 2016;**8**:77-101. Available from: https://www.researchgate.net/publication/312030138

[6] National Institute for Pharmaceutical Research and Development Scheme of service and condition of service. 2010. pp. v-vi

[7] Halisa M, Akovab O, Tagraf H. The relationship between ethics and quality: Conflicts and common grounds. Serbian Journal of Management. 2007;**2**(2):127-145. Available from: https://www.sjm06.com/SJM20ISSN1452-4864/2_2_2007

[8] Tyco Electronics Quality Management Process. Quality Manual 102-1. Rev P, EC 0990-1677-02. 2003. pp. 9-11

[9] Yousef N, Yousef F. Using total quality management approach to improve patient safety by preventing medication error incidences. BMC Health Service Research. 2017;**17**(1):621. DOI: 10.1186/s12913-017-2531-6

[10] Diaz JEC. Importance of training, learning and education for total quality management (TQM) implementation. In: A paper presented at VI Congreso Nacional y Primero Internacional de Investigación en Ciencias Administrativa Mesa 2: Innovación y Tecnología. 2002. pp. 1-25

[11] Patanjali M, Asha P. The role of leadership in implementing Total quality management (TQM) in higher education: A review. European Academic Research. 2013;**1**(8):2149-2166

[12] Bigliardi B, Galati F. The implementation of TQM in R&D environments. Journal of Technology Management & Innovation. 2014;**9**(2):157-171

[13] Jasmine T, Samear P, Ron T. The influence of organizational structure on the effectiveness of TQM programs. Journal of Managerial. 1999;**11**(4):440-453

[14] ISO/IEC 17025:2005. General Requirements for the Competence of Testing and Calibration Laboratories. Geneva: International Organization for Standardization; 2005

[15] Ahaotu SM, Pathirage C. Importance of leadership in effective implementation of TQM in the Nigeria construction industry presented at a conference at the University of Salford. 2015:1-15. Available from: http://usir.salford.ac.uk/35628