A SURVEY OF QUALITY MANAGEMENT PRACTICES OF PHARMACEUTICAL MANUFACTURING COMPANIES IN KENYA

TANUI, PAUL KIPTUM

A Research Project Report Submitted in Partial Fulfilment of the Requirements for the Award of Degree of Master of Business and Administration, School of Business, University of Nairobi

OCTOBER 2008

DECLARATION

I, the undersigned, declare that this is my original work and has not been submitted for a degree in this or any other University for examination.

Signed: Tanui _____ 22/11/08

Tanui Paul Kiptum
D61/8338/2006

Date

This project has been presented for examination with my approval as the university supervisor.

Signed: _____ 24/11/2008

Onserio S. Nyamwange
Lecturer,
Department of Management Science,
University of Nairobi.

Date

DEDICATION

I dedicate this work in memory of my parents late Mr & Mrs Joseph Tanui.

ABSTRACT

The objective of the study was to identify and determine the extent of implementation of various quality management practices by pharmaceutical manufacturing companies in Kenya. The study also aimed at determining the challenges of implementing quality management practices by pharmaceutical manufacturing companies in Kenya.

The research methodology was based on a survey study approach for establishing quality management practices and challenges of implementation by pharmaceutical manufacturing companies. Surveys are concerned with describing, recording, analyzing and interpreting conditions that either exist or existed. An open ended and closed ended questionnaire was used to collect data; the questionnaire was divided into 2 sections which were answered by the top management and the lower level management

This study reveal the importance pharmaceutical firms attach to quality improvement practices. The study also revealed that the basic elements of quality management such as an appropriate infrastructure or quality system encompassing the organizational structure, procedures, process and resources; systematic action necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality are indeed vital for any quality management activity. In relation to top commitment by top management in ensuring there is quality improvement in the firm, the total counts agree (both strongly agree and agree) was 25. This make 83.3% of the total counts, which indicate that management is actively involved in quality improvement. This when compared to lower level management, the total count strongly agreeing were only 6 (20%). This study therefore reveals that top management is generally more supportive to quality management practices as compared to lower level management although different levels of perceptions permeate the entire management spectrum.

ACKNOWLEDGEMENT

I wish to acknowledge and thank my supervisor, Mr. Onserio Nyamwange and Mr. M. Mwangi whose incisive reading and constructive critiques of the project in progress have been invaluable. The two have been remarkably patient, considering the time this research project has taken to come to fruition, providing consistent guidance, constructive feedback and helpful advice during the successive stages of this work. I also wish to acknowledge and thank Sarah Njeri and Lillian Kinyanjui without whose efforts the preparation of many drafts of this work would not have succeeded. I am deeply indebted to the employees and management of all the pharmaceutical firms who graciously gave their time to be interviewed or complete the research questionnaires.

TABLE OF CONTENTS

LIST OF ACRONYMS

BS:	British Standards
CGMP:	Current Good Manufacturing Practices
DTI:	Department of Trade and Industry
FDA:	federal Food and Drug Administration
GCP:	Good Clinical Practices
GLP:	Good Laboratory Practices
GMP:	Good Manufacturing Practices
GDP:	Gross Domestic Product
HoD:	Head of Department
ISO:	International Organization for Standardization
JIT:	Just-In-Time
MSH:	Management Sciences for Health
MRP:	Material Requirements Planning
MOH:	Ministry of Health
MC Ns:	Multinational Corporations
PPB:	Pharmacy and Poisons Board
PIMS:	Profit Impact of Market Strategy
QA:	Quality Assurance
QCs:	Quality Circles
QC:	Quality Control
QMS:	Quality Management Systems
R & D:	Research and Development
SOPs:	Standard Operating Procedures
SPC:	Statistical Process Control
SPSS:	Statistical Program for Social Scientist
TQCS:	Total Quality Customer Service
TRIPS:	Trade-Related Aspects of Intellectual Property Rights
USA:	United States of America
USEPA:	United States Environmental Protection Agency
WHO:	World Health Organization
WTO:	World Trade Organization

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

The search for a universal definition of quality has yielded inconsistent results. Such a global definition does not exist: rather, different definitions of quality are appropriate under different circumstances (Reeves, 1994). Broadly defined, quality refers to the ability of a product or service to consistently meet or exceed customer expectations (Stevenson, 2002). The word 'quality' seems to trigger a multitude of definitions.

Crosby, et al (1997) has defined quality as the totality of features and characteristics of a product or service that bear on the ability to satisfy stated or implied needs. This definition suggests that quality must conform to requirements to satisfy the needs of users or anyone in contact with the product or service.

For researchers and practitioners, understanding the nature of quality is more than a philosophical issue. Research conducted for the profit impact of market strategy (PIMS) program has led to the conclusion that in the long run, the most important single factor affecting a business unit's performance is the quality of its products and services, relative to those of competitors (Buzzell & Gale, 1987).

Quality management practices have been described as a collective interlinked system of practices that is associated with organizational performance (Dean and Bowen, 1994). In this respect, several studies have attempted to identify the key quality management practices on which the success of a quality strategy is based (Saraph et al, 1989). Quality management is thus the approaches and actions that are undertaken by an organization's management with the aim of improving quality. It is these management-initiated approaches that distinguish leading-edge companies from poor performers who may be pushed out of the competition (Adam and Ebert, 2001).

It is a company's management job and responsibility to create a culture of quality in an organization. This function cannot be delegated to technicians or workers. The idea is to help all in an organization to concentrate on doing their job right the first time. Without quality management, an organization's efforts to improve or control quality are likely to fail (Crosby et al, 1997). According to Application Guidelines Malcolm Baldrige National Award (1991), various examination categories, items and point values are identified for the Malcolm Baldrige National Quality Award. These include leadership, information and analysis, strategic quality planning, human resource utilization, quality assurance of products and services, quality results and customer satisfaction.

Benson et al (1991) have proposed an organization–theory explanation for how quality is managed in organizations. They propose a system – structural model of quality management that relates organizational quality context, actual quality management, ideal quality management, and quality performance. Lakhal et al (2005) have identified critical quality management practices linking them in a model and testing the relationship empirically. Numerous empirical studies have been conducted in the past ten years to gauge the development and majority of quality management practices particularly among manufacturing firms and correlation with overall organization performance has been documented in the work of Rahman and Sohal (2002).

1.1.1 Quality Management in the Pharmaceutical Industry

The quality of pharmaceuticals has been a concern of the World Health Organization (WHO) since its inception. The setting of global standards is requested in Article 2 of the WHO Constitution, which cites as one of the organization's functions as the development, establishment and promotion of international standards with respect to food, biological, pharmaceutical and similar products. Every government allocates a substantial proportion of its total health budget to drugs. This proportion tends to be greatest in developing countries, where it may exceed 40% (WHO, 2004).

Good Manufacturing Practices (GMPs) are the part of quality assurance that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and required by the drug regulatory authority. GMP rules are directed primarily at diminishing the risks, inherent in any pharmaceutical production that cannot be prevented completely through the testing of final products. Such risks are essentially of two types: cross-contamination (in particular by unexpected contaminants) and mix-ups (confusion) caused by incorrect labels on containers or human error (Management Sciences for Health, 1997). Since 1968, WHO has attempted to standardize the GMPs of various countries into a single list. These GMPs are applicable to all pharmaceutical manufacturing companies. Although these GMPs are written for the pharmaceutical industry, when a manufacturer produces medicines, it should duplicate the standards that went into the manufacture of that product, not just those that apply to the final product (WHO, 2004).

Quality control of pharmaceuticals depends on meticulous adherence to written procedures in carrying out all operations. Quality must be designed into a product from the earliest stages: it cannot be ensured in the final product if GMPs were not present throughout the production process. Raw materials must be purchased from reputable suppliers and certified to conform to WHO standards of quality. Whether or not local quality control testing facilities exist in a resource constrained country (as happens in most developing countries), copies of the quality control analysis report of raw materials should be required from the supplier at the times of purchase (Polderman, 1990).

Without assurance that these drugs are relevant to priority health needs and that they meet acceptable standards of quality, safety and efficacy, any health service is evidently compromised. In developing countries, considerable administrative and technical effort is directed to ensuring that patients receive effective drugs of good quality. It is crucial to the objective of health for all that a reliable system of drug control is brought within the reach of every country (WHO, 2004).

The supply of essential drugs of good quality was identified as one of the prerequisites for the delivery of health care at the International Conference on Primary Health Care in Alma-Ata in 1978. Similarly, the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, and WHO's Revised Drug Strategy, adopted by the World Health Assembly in May 1986, identified the effective functioning of national drug regulation and control systems as the only means to assure safety and quality of medicines (Management Sciences for Health, 1997). According to Polderman (1990), the manufacture of such dosage forms, the drugs, requires a thorough knowledge of the fundamentals of the relevant processes. Because of the great diversity of the substances that have to be handled and of the processes involved this knowledge should be broad-based. The main facets of it can be briefly described as: the development of a formulation, the production of the drugs and the quality control of the drugs. Inevitably, such diversity gives rise to a need for an integrated management approach that places quality assurance at the centre of its operations (Polderman, 1990).

1.1.2 Pharmaceutical Manufacturing Industry in Kenya

Kenya's Health Policy Framework (MOH, 1994) outlines the goal of the health sector policy to 2010 as to promote and improve the health of all Kenyans through the deliberate restructuring of the health sector to make all health services more effective, accessible and affordable. This framework outlines comprehensive health sector reforms, amongst them strengthening the policy role of the central MOH; decentralization and capacity strengthening of provincial and district levels; re-orientation, re-training and re-deployment of health manpower; and adoption and implementation of the National Drug Policy as the guiding document for legislative reforms, staff development and management improvements in pharmaceutical services (MOH, 2007).

To improve domestic accessibility of essential medicines and promote pharmaceutical exports, the government will ensure an enabling environment for local pharmaceutical production. Some of the activities to implement accessibility of essential medicine is to strengthen capacity for cGMP compliance and encourage international accreditation for the 34 registered local manufacturers; provided incentives for local pharmaceutical

production of essential medicines to improve their affordability and availability, and effectively utilize WTO/TRIPS flexibilities to promote local manufacture of essential medicines (MOH, 2007).

MOH (2007) further provides that medicines shall meet internationally acceptable standards of quality, safety and efficacy, and shall be provided according to legal requirements and professional standards. This was achieved through development and implementation of a coherent pharmaceutical quality assurance system, enhancement of the capacity for pharmaceutical quality control, and development and promotion of the use of quality management principles with regard to pharmaceutical quality assurance.

1.2 Statement of the Problem

There are several peculiar features of the pharmaceutical industry, which invite government intervention in developed as well as developing countries. In poor countries in particular, the pressure to economize on drug purchases has led those countries to overlook the system of innovation and rigorous quality assurance, which has grown tremendously in the developed countries: thus, the large drug multinationals are subjected to a large battery of controls. The main factors which has lead pharmaceutical manufacturers in developing countries to trail their Multinational Corporations (MNCs) counterparts in developed countries their inferior operational efficiency, poor quality assurance systems and limited use of modern and appropriate technology (Lall, 1985).

The regulatory authorities, governments and other interested parties are concerned with the implementation of concepts of Good Manufacturing Practices (GMPs). Various governments in the developed world require rigorous quality management practices (WHO, 2004). The current Good Manufacturing Practices (cGMP) and effluent emission regulations of the U.S. Food and Drug Administration (FDA) and manufacturing effluent discharge and emission regulations of the U.S. Environmental Protection Agency (U.S. EPA) require contained manufacture, use and disposal of pharmaceuticals with the goal of minimizing the release of pharmaceutical waste into the environment (Valagaleti et al,

2002). MOH (2007) requires that pharmaceutical manufacturing of medicines conform to quality, safety and efficacy standards comparable to international standards.

Musau (2003) based on a case study of quality management practices at Colgate-Palmolive Kenya, recommended the need for Kenyan manufacturers to reassess the level of entrenchment of quality management practices in the organizations' activities. He notes that for an organization to achieve competitive advantage it has to have all prerequisites of quality management working hand in hand. In yet another study on Continuous Improvement Climate Survey in Kenya, Mwihaki (2005) suggests further research on local manufacturing companies at different stages of implementing quality management strategies.

Stevenson (2002) asserts that quality management practices have been identified as a way for companies to improve their competitiveness. However, there have been noted inconsistencies in blind pursuit of quality management practices. Overzealous advocates may focus attention on quality even if other priorities may be more important. Furthermore, quality management programs may not be linked to the strategies of the organization in a meaningful way. Thus in the past quality-related decisions have not been tied to market performance. This leads to the questions: What quality management practices do pharmaceutical manufacturing companies in Kenya employ in the manufacture of pharmaceutical products and what are the challenges of the implementation of these quality management practices?

1.3 Objectives of the Study

i) To identify and determine the extent of implementation of various quality management practices by pharmaceutical manufacturing companies in Kenya.

ii) To determine the challenges of implementing quality management practices by pharmaceutical manufacturing companies in Kenya.

1.4 Importance of the Study

This study sought to investigate various quality management practices applied by the companies in the pharmaceutical industry. These practices tend to improve the performance of the company practicing these quality management techniques in its day-to-day activities. Increased performance will always bring about increased productivity, company performance and profitability.

This study will be useful to Kenya's pharmaceutical regulatory authority whose interest is to ensure supply of quality safe and efficacious medicines to the public. The academia and research institutions in the area of quality management specialty will gain an insight from this study on the various quality management practices applied by pharmaceutical manufacturing companies as well as challenges encountered in the process of their implementation.

The researcher's main objective was to identify various management practices employed by pharmaceutical manufacturing companies. The study targeted the pharmaceutical industry, which is currently facing a myriad of challenges. The findings of the study can be applied in the pharmaceutical industry and related industries such as the chemical industries. As a result, therefore, increased performance as a result of implementing quality management practices will tend to spur economic development and attract investors in the local manufacturing industry.

For the workers, training opportunities occur thus this enhances their skills and expertise. There also occurs an increased level of technology transfer. High quality goods produced in the manufacturing facility will certainly satisfy the final consumer. Furthermore since pharmaceutical products are sensitive to the health of patients high quality drugs will ensure that patients' access to high quality medicines is guaranteed.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Many leading nations, such as the United States, Japan and Germany have fought the global pressures of competition by becoming increasingly technologically advanced, moving up-market to more value-added products, and upgrading the skills of their domestic workforce (Enright, Scott and Dodwell, 1997; Pun and Lee, 1997). The impact of quality is so enormous that can it and does affect a company's competitiveness both locally and globally.

The profile of the quality management literature is unbalanced with a strong predominance of the descriptive and prescriptive writings (Aragon, et al, 1993). The literature is based largely upon case studies, and the personal experience of the practitioners and quality consultants. Numerous case studies have been done across industries to describe the successful implementation such Quality Management System Initiatives such as of ISO (Aragon, et al, 1993). Based on personal experience several generic frameworks such as top leadership commitment, customer focus, continuous improvement amongst others have been proposed for implementation of quality management systems to help companies to achieve quality, productivity and competitive advantage (Crosby, 1979)

Early studies focused primarily on studying quality practices in developed countries such as Japan and USA (Benson et al, 1991; Hull et al, 1988). Lately literature has extended its scope by comparing QMS in other developed and developing countries, for example India (Rao, et al, 1997). One of the concept that have gained prominent is Total Quality Management (TQM) which has been defined as quality centered, team driven, customer focused, fact-based, senior management laid process to achieve an organization's strategic goal (Anderson, 1994). Total quality management has been one of the most prominent developments in the management field in the last two decades. Beginning in Japan in the early 1980s, TQM has diffused into Western countries and reached its heyday in the 1990s as suggested by the number of publications, which discuss TQM and

related topics (Martinez-Lorente et al., 1998). As a set of principles, TQM has been deployed into certain practices, which can be implemented in organizations. Researchers have developed various models of TQM practices and have used them to measure the level of adoption of quality management practices in organizations (Anderson et al., 1994).

2.2 Defining Quality

Quality means different things to different people. This is the argument put forward by various students of quality. For instance, Lysonns and Gilligham (2003), point out that there are numerous definitions of quality. These writers further argue that these alternative definitions often overlap and may conflict. According to the American Society for Quality Control (1999), quality is a matter of relationship management. The society defines quality as the ongoing process of building and sustaining relationships by assessing, anticipating, and fulfilling stated and implied needs. The society argues that even those quality definitions which are not expressly relational have an implicit relational character, hence the reason why people and organizations try to do the right thing right, on time, every time; build and sustain relationships; seek zero defects and conformance to requirements; seek to structure features or characteristics of a product or service that bear on their ability to satisfy stated and implied needs. Winder et al (1996) concurs with the society. According to these scholars, the focus of continuous improvement is the building and sustaining of relationships. They further argue that it would be difficult to find a realistic definition of quality that did not have a fundamental express or implied focus of building and sustaining relationships. These researchers concretize their arguments by saying that quality is the customers' perception of the value of the suppliers' work output. They further argue that you cannot separate the process and the human factor. They believe that quality, when built into a product, generates emotions and feelings within those who have taken part in its creation. Finally, they conclude that when you have made something that you are proud of, when you have produced a product that brings smiles to your customers and then you have achieved quality. You will know it, they will know it, and each of you will prosper from it. Persig (1974), on his part, define quality, quite interestingly. He argues that even though quality

cannot be defined, one knows what it is. It is neither mind nor matter, but a third entity independent of the two. Juran (1974) and Crosby (1979) on their part define quality in a more summarized way arguing that quality is the conformance to requirements and fitness for use respectively.

Perhaps the most celebrated definition of quality is that given by the American Society for Quality, which is shared by the ISO 8402 (1986). These two organizations define quality as the totality of features and characteristics of a product or service that bear on its ability to satisfy given needs. Literature shows that the single factor affecting a business' competitive ability is the quality of its products and services, relative to those of competitors (Meredith, 1992). According to Meredith (1992), quality products or services leads to more customer satisfaction; enhances the reputation of the firm; protects the firm from competition; minimizes health and safety liabilities and risk; improves worker morale; reduces scrap and waste; smoothes work flows; improves control and reduces a variety of costs.

The understanding and consequent desire to attain benefits of superior quality has been the struggle of many firms since the onset of the industrial revolution. This effort was moved a step higher after the Second World War when many governments suffered massive defeats caused by weapon failures. Britain, which was faced by many accidental detonations in their weapons factories embarked on a search for solutions to this quality problem. This eventually led to the development of BS 5750 in 1979, which also changed to be the current ISO 9000 in 1987.

2.3 Quality Management Practices

According to Benson et al (1991), quality management is becoming a top priority in many U.S firms. Since quality management is an organization wide function, organization theory should be used to describe, explain and improve it. Organization theory has contributed significantly to the practice of quality management, and in turn, improved quality performance and company performance. Benson et al (1991) proposes a model of quality management comprising a system-structural view of quality

management. This system-structural view explicitly considers the organization's external context and its impact on the organization. With quality problems being driven by external factors such as customer demands, competitive pressures and government regulation, the system-structural view is particularly helpful in explicating a theory of quality management.

The basics element of quality management is: an appropriate infrastructure or quality system encompassing the organizational structure, procedures, process and resources; systematic action necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality. The totality of this action is termed as quality assurance, which serves as a management tool. In contractual situations, quality assurance also serves to generate confidence in the supplier. The concepts of quality assurance, Good Manufacturing Practices (GMP) and Quality Control (QC) are interrelated aspects of quality management. An organization will benefit from establishing an effective quality management system (Department of Trade and Industry, British Government, 2007).

The cornerstone of a quality organization is the concept of the customer and the supplier working together for their mutual benefit. For this to become effective, the customer-supplier interfaces must extend into and outside of, the organization, beyond the immediate customers and suppliers (DTI, 2007).

2.3.1 Top Management Commitment

The process by which top managers allocate their limited attention among a wide variety of potential strategic issues is critical to understanding organizational adaptation and change (Dutton, 1988). Berman et al (1995) have shown that executive culture and top management leadership are significant determinants of quality management commitment and impact. From top-level administrators to front-line managers, quality management practices have permeated the entire organization – private or public. Quality management has been viewed as a way to improve overall service delivery, generates cost savings and instills a common vision for the organization (McGowan, 1995). There are many routes

to successful quality improvement and not all organizations follow the same formula. Still, there is sufficient experience with quality efforts in American organizations to generalize about what a quality process entails (Dobbs, 1994).

Shetty (1991-1992) summarized principles generally found in quality-conscious organizations. Top in the list is top management commitment. Shetty argues that top management must establish and communicate a clear vision of organizational philosophy; make it clear that everyone must be personally committed; allocate resources, define roles and responsibility, invest the time to learn about quality issues; encourage communication between management and employees, among departments and various units and customers, be a good role model in communication and action, and monitor the process.

Powell (1995) has listed committed leadership amongst the twelve Total Quality Management (TQM) factors. He states that what is critical is a committed leadership: a near-evangelical unwavering, long-term commitment by top managers to the philosophy, usually under a name something like Total Quality Management, Continuous Improvement (CI) or Quality Improvement (QI).

2.3.2 Organization for Quality

In the face of changing competitive conditions, many firms are pursuing quality management practices to regain their competitive edge (Victor et al, 2000). These firms are discovering that effective implementation is not guaranteed. Many attempts fail to achieve desired gains in quality and efficiency (Griffin, 1988). Victor et al (2000) proposes that through poor leadership, inappropriate training, lack of resources, confusion of program goals and cultural resistance that cause quality management practices failure, none is more fundamental than the cause that underlie the difficulty of implementation having as its basis the integration of doing and thinking (Best, 1990). Total quality management significantly alters the way jobs are designed requiring new behaviors, roles and responsibilities for all organizational members (Koike, 1988).

2.3.2.1 Process Management

Process management is a way, in which an individual, a group, a project, or an organization thinks about, and managers, its work activities. It is based on the following process management premise: the quality of the product is governed primarily by the quality of the process used (Shapiro, 1995).

Most organizations today do not manage the process, but instead their products. This is the classical American management style documented and described in many books. Based on the process management premise, however, process management can be said to be fundamentally different from product management in that customer satisfaction is more than just meeting requirements specifications; it is focusing on finding ways to delight the customer. Based on process management, suppliers know whom their customers are (internal or external) and what they need and practices are documented and understood by those performing the work. In addition, people have the skills needed to do their tasks successfully and are committed to following the process because they know it will get them through good times and bad (Shapiro, 1995).

Work is completed when the defined exit conditions have been met, not when there is no more money or time and process and product measures are taken to compare quality, schedule and cost (actual) to estimates. Corrective actions focus on process problems and process solutions not on blaming people, the environment, or the tools process changes are managed and controlled (Monden, 1989).

2.3.2.2 Just-In-Time (JIT) Manufacturing

One of the world's leading experts on improving the manufacturing process, Shingo (1989), created with Taiichi (1989) many of the features of just-in-time manufacturing methods, systems, and processes that constitute the Toyota production system. Much of Shingo's work is documented in the books he has written; such as the study of the Toyota production system from an industrial engineering viewpoint (1989).

Monden (1989) is credited with introducing the JIT concept to a broad audience in the United States. His early work focused primarily on a limited set of JIT practices related to shop floor activities. This series of articles described the philosophy of JIT, the Kanban system, production smoothing in JIT and set-up-time reduction. He also emphasized the importance of small lot sizes, mixed model production, multifunction workers, preventive maintenance, and JIT delivery by suppliers.

In a study of small and large US manufacturers, White et al (1999) has documented and studied ten management practices that constitutes the JIP concept used to examine implementation of JIT manufacturing systems. They also assert that the 10 JIT management practices implemented differ between the two groups of manufacturer size and an association exists between the JIT practices implemented and manufacturer size. Moreover, the changes in performance attributed to JIT implementation vary, depending on implementation status of specific JIT management practices and manufacturer size. Overall, the findings suggest that specific JIT management practices might be more appropriate for implementation depending on manufacturer size. Understanding the relationships identified and other relationships associated with JIT implementation process enables factory managers to more effectively manage and control their organizations for success.

Flynn et al (1980) proposes that the use of total quality management practices will improve just-in-time (JIT) performance through process variance reduction and reduced rework time and that JIT practices will improve quality performance through problem exposed and improved process feedback. They have demonstrated that TQM and JIT practices interacted.

2.3.3 Employee Training

It has become a widely held premise that people provide organizations with an important source of sustainable competitive advantage and that the effective management of human capital, not physical capital, may be the ultimate determinant of organizational performance (Adler, 1988; Reich, 1991). Given the team-based problem-solving nature

of total quality management programs, firms adopting a quality strategy must facilitate employee interaction and information exchange (Youndt et al, 1996). The value of human capital may be especially apparent in modern, manufacturing organizations that have invested heavily in production innovations such as advanced manufacturing technology, statistical process control and computer numerically controlled machine tools. Such initiatives tend to depend heavily on employee skills and commitment as key components in the value creation process (Snell, 1992).

Powell (1995) has identified increased employee training as a critical TQM factor and that increased employee training should include TQM principles, team skills and problem solving. Employee training should be directed at establishing commitment human resource systems (Arthur, 1992). Commitment human resource systems shape desired employee behaviours and attitudes by forging psychological links between organizational and employee goals. In other words, the focus is on developing committed employees who can be trusted to use their discretion to carry out job tasks in ways that are consistent with organizational goals (Organ, 1988)

2.3.4 Employee Participation

Employee participation is any quality improvement initiative is critical for its success. Several authors have identified employee empowerment, formation of quality circles and employee fulfillment as critical ingredients for successful employee participation in quality management practices.

2.3.4.1 Employee Empowerment

One of the most frequently referenced definitions of employee empowerment is that offered by Conger and Kanungo (1988). They define empowerment as a process of enhancing feelings of self-efficacy among organizational members through the identification of conditions that foster powerlessness, and through their removal by both formal organizational practices and informal techniques of proving efficacy information. This definition implies strengthening the effort-to-performance expectancy or increasing

employee feeling of self-efficacy. According to Conger and Kanungo (1998), the effect of empowerment is the initiation and persistence of behavior by empowered employees to accomplish task objectives. This definition is rooted in management theory of power and authority delegation that gives an employee the right to control and use organizational resources to bring about desired organizational outcomes.

Thomas and Velthouse (1990), however, argued that the concept of empowerment is much more complex and could not be fully explained in a one-dimensional construct such as self-efficacy. They therefore define empowerment as an intrinsic task motivation that manifests itself in four cognitions (meaningfulness, competence, impact and choice or self-determination), reflecting an individual's orientation to his or her work roles. By intrinsic task motivation, they mean, a positively valued experiences that an individual derives directly from a task that produces motivation and satisfaction.

Meaningfulness is the value of the task goal or purpose in relation to the individual's own ideals or standards, and competence is the degree to which a person can perform task activities skillfully. Impact, on the other hand, is the degree to which behavior is seen as making a difference in terms of accomplishing the purpose of the task, while choice or self-determination is the causal responsibility for a person's actions. It reflects independence in the initiation and continuation of work behavior and processes (Connell, and Ryan, 1989).

Employee empowerment literature identifies contextual factors and strategies that promote and support empowerment. For example, Burke (1986) suggests that a way to empower employees is to express confidence in them together with establishing realistic high performance expectations for them. Best (1990) adds the creation of opportunities for employees to participate in decision making, and giving employees autonomy from bureaucratic constraints as empowerment strategies. Comparatively, Bemis and Nanus (1985) suggest the setting of performance objectives for employees that are challenging and inspiring and also, Kantar (1979), Hackman and Oldham (1975) suggest performance-based reward systems and enriched jobs that provide autonomy and control, task identity, opportunities for career advancement and task meaningfulness as ways to

empower employees. At the organizational level, however, Kiore (1988) suggest that empowerment could be achieved through employee selection and training programs designed to provide required technical skills together with a culture, which encourages self-determination and collaboration instead of competition.

Empowering the workforce involves giving employees a degree of control over the organization's operation. When empowered, employees feel they are an active part of the organization's decision-making process and they have an organizational sense of "family". Once empowered, employees begin to take pride and ownership in tier work, which may lead to improvement in their job performance, which then may increase overall organizational quality. As employees become more involved in the organization, they become self-motivated and do not require as much direct praise or monitoring from managers. As a part of the empowerment process, employees are permitted more management participation (Shapiro, 1995).

2.3.4.2 Quality Circles (QC)

In a longitudinal study, examining the impact of work teams on manufacturing performance Raja et al (1996) found out that quality and labour productivity improved over time after the formation of work-teams. They point out that quality circles where membership is voluntary is most effective especially since the team is specific work-related and is tasked with problem solving for quality and productivity related issues and cost reduction.

Griffin (1988), defines quality circles (QC) as small groups of volunteers from the same work area who meet regularly to identify, analyze and solve quality and related problems in their area of responsibility. They usually consist of eight to ten members and meet once a week during normal working hours. Moreover, members of QCs usually receive some form of training in problem-solving techniques. Previous research has also clearly documented that QCs are not as much as Japanese invention as an American Invention of which the Japanese were the first adopters (Cole, 1980).

2.3.5 Supplier Quality Management

A central theme of quality management is that technical and human aspects of a process must be managed in concert. Complementing the design of efficacious development processes, work design practices that foster participation of key stakeholders and empowerment of employees need to be established (Ravichandran & Rai, 2000). The attempt to use improved quality to gain a competitive advantage has led firms to develop quality-sensitive industrial contracts. The quality of delivered materials and parts and its control through sampling or quality control procedures are thus important issues to reckon with in the negotiation of industrial contracts (Reyniers et al, 1995).

Current practice in quality management and its control emphasizes the use of statistical control techniques (control charts, acceptance sampling etc), which seek to detect deviations from agreed on quality standards (Reyniers, 1995). Chew and Pissano (1990) suggest that as an alternative to vertical integration; longer-term contracts with power suppliers may be required to improve quality. In practice the quality of the suppliers and considered important and in contractual supply agreements, clauses are inserted to provide incentives for the suppliers to comply with the terms of negotiated contracts. For example, some contracts stipulate that payments will be made after and as a function of delivered quality (Reyniers, 1995).

Over the past decade, there is growing evidence that to be competitive manufacturing firms are moving away from a traditional approach of adversarial relationships with a multitude of suppliers to one of forging longer-term relationships with a few select suppliers (O'neal, 1989). Firms such as Eerox, Motorola, General Electric, Ford and others are reducing their supplier base and looking to a few select suppliers to help them achieve a stronger competitive position (Emshwiller, 1991).

The goal is to secure valued resources and technologies of the selected suppliers in situations that preclude the option of vertical integration due to resource limitations and managerial constraints (Dwyer, 1993). Apart from being able to harness the strengths and skills of suppliers to their advantage (Dwyer, Schurr and Oh, 1987), manufacturers in

long-term relationships also benefit from improved quality and process performance and continuous cost reductions (Newman, 1988).

2.3.6 Customer Focus

Internal customer focus is a key ingredient quality management practices. However, Lewis (1989) points out that emphasizing focus is one thing; delivering it is another. In fact, he considers that emphasizing focus is not most appropriate approach to adopt. Thus management policies that enhance internal customer-based focus often prove to be a firm's best marketing strategy. Christopher et al (1991) go further than this to describe a new relationship between quality, customer service and marketing. They argue that quality is also a key linkage in the exchange relationship between the organization and its employees as customers. They maintain that unless management can bring these activities together with new forms of collaboration and cross-functional coordination, there can be no sustainable competitive advantage.

Just as customer service leads to customer satisfaction, internal customer service leads to employee satisfaction. Internal customer service is the service we provide to fellow employees and other departments within our own organizations, as well as our suppliers and anyone else with whom we work to get our jobs done (Buzzell, 1987). He also asserts that to achieve legendary internal customer service, one has to weaken the tendency to build territorial walls and adopt ways of creating forums to share information, practice proactive information-sharing and create or contribute to, an environment in which status is accorded to those who share freely and not to build walls (Buzzell, 1987).

Competitive advantage is achieved by organization, which needs to know who its internal customers are, what they expect and how well its performance from the customer's point of view is (Buzzell, 1987). The concept of internal customer is significant as it dramatically makes the case that an organization cannot meet the needs of its external customers if each output passed within the company is deficient. For example, if each handoff within the organization is less than 100%, the resultant output will always fall short of customer expectation (Buzzell, 1987).

Drucker (1954) stated that the only reasons for business to be in business were to innovate and satisfy customers at a profit. Kotler (1967) launched the new marketing concept, which stated that corporate profit came out of satisfying customer needs through integrated marketing activities. Profit did not come out of sales volume alone, which was the old marketing concept. Towards the end of the 1970s Gronroos presented the service-marketing concept (Gronroos, 1979), which held some distinct differences from the traditional product-marketing concept. During the 1980s, a group of Scandinavian marketing researchers realized that the service-marketing concept was valid and relevant for business-to-business marketing, in particular when studying buyer and seller relationships. What today is called relationship marketing as understood and defined by the Nordic School of Thought is fundamentally different from the traditional 4P marketing paradigm (Gronroos, 1997). This rationale emerged as a new paradigm within marketing.

Numerous studies have proven that satisfied customers relate their positive experience to three people, whereas dissatisfied customers tell eleven to thirteen people about their negative experience (Kotler et al, 1999). Understanding the customer expectations is often referred to as listening to the voice of the customer and requires identification of a whole set of product/ service characteristics that the customer needs, his/her level of expectations, relative importance and satisfaction derived (Kotler, et al, 1999).

To become a master of customer understanding, you have to increase both the quality and quantity of your processes. Three important strategies to focus on include, developing strong links to both the core and the fringes of your market, use ethnography (the application of principles of anthropology to study the behavior of customers to gain new insights) and include customers and customer knowledge throughout the design process (Kotler et al, 1999).

2.3.7 Quality System Improvement

Manufacturing systems typically contain processing and assembly stages whose output quality is significantly affected by the output quality of preceding stages in the system (Zanktek et al, 2002). The use of statistical quality control and related quality-improvement methods has become widespread in recent years as a result of increased emphasis on improving quality and product competitiveness. An important premise underlying these methods is that reducing process and product variability leads to improved products and reduced quality costs. Reducing variability is also known to favorably affect operating metrics such as productivity, cycle time and capacity. Tagaras and Lee (1996) recognize that the output quality of some stages in multistage manufacturing systems is significantly affected by the output quality of proceeding stages. Most of the literature on quality and quality improvement however is restricted to single-stage models or assumes the absence of quality linkages across stages. A notable exception is Hawkins (1993), who proposes a procedure for monitoring process quality in manufacturing systems where the measures of output quality are correlated across stages.

Zanktak et al (2002) proposes and validates a procedure for measuring the impact of each stage's performance on the output quality of subsequent stages, including the quality of the final product. The procedure builds on the precedence ordering of the stages in the system and uses the information provided by correlations between the product measurements across stages.

2.3.7.1 Quality Assurance Program

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the objects of ensuring that pharmaceutical products are of the quality required for the intended use. Quality assurance in any organization depends on many factors (Frederick Garfield, 1994).

For a quality, assurance program to be successful there must be commitment by the management and co-operation by the staff, a rational foundation for the program, and recognition of objectives. According to WHO (2004) quality, assurance incorporate good manufacturing practices amongst other factors. The system of quality assurance appropriate to the manufacture of pharmaceutical products should ensure that pharmaceutical products are designed and developed in a way that takes account of the requirement of good manufacturing practices (GMPs) and associated codes such as those of good laboratory practices (GLPs) and good clinical practices (GCPs). Furthermore, all production and control operations are clearly specified in a written form and properly documented. Management responsibilities should also be specified in job descriptions. All necessary controls on starting materials, intermediate products, and bulk products and other in process control, calibration and validations are carried out. The finish product is correctly processed and checked, according to defined procedures.

Pharmaceutical products are not sold or supplied before the authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical products (Polderman, 1990).

In addition, satisfactory arrangements should exist to ensure, as far as possible, that the pharmaceutical products are stored by the manufacturer, distributed, and subsequently handled so that quality is maintained throughout their shelf life. An effectively quality assurance programme should entail a procedure for self-inspection and / or quality audit that regularly appraises the effectiveness and applicability of the quality assurance system. All deviations must be reported, investigated and recorded. Regular evaluations of the quality of pharmaceutical products should be conducted with objective of verify the consistency of the process and ensuring its continuous improvement. All system changes that may have an impact on product quality must be approved through a procedure of change control. The pharmaceutical manufacturer must assume responsibility for the quality of the pharmaceutical products that it manufacturers so as to ensure that they are fit for their intended use complying with the requirement of the marketing authorization and do not press patience and risk due to inadequate safety,

quality and efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment of all the staff in many different departments and at all levels with the company, the company's suppliers and the distributors (MSH, 1997).

To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating good manufacturing practices (GMP) and quality control (QC). It should be fully documented and its effectiveness monitored. All parts of the quality assurance system should be adequately staffed with competent personnel, and should have suitable and sufficient premises, equipment, and facilities (WHO, 2004).

2.3.7.2 Good Manufacturing Practices

WHO (2004) defines Good Manufacturing Practices (GMP) as that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full tractability of a product through batch records and distribution records; and systems for recall and investigation of complaints (Gillian, et al, 1997).

GMP regulations address issues including record-keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner, which makes sense for each individual business (Junker, 1997).

GMP is also sometimes referred to as "cGMP". The "c" stands for "current," reminding manufactures that they must employ technologies and systems, which are up-to-date in order to comply with the regulation. Systems and equipment used to prevent contamination, mix-ups and errors, which may have been "top-of-the-line" 20 years ago, may be less than adequate by today's standards (Junker, 1997). One step in the GMP Lifestyle is to reinforce what is learned in training. This falls on the managers and supervisors in a plant. Therefore, it is important that managers and supervisors be involved in training, so that they can support it through reinforcement. The other step is to audit to ensure that your efforts have provided adequate controls by auditing audit fall in the following three categories: personal, whereby every individual does a self-check to make sure that he / she is complying with all appropriate standards; internal audit, which should be performed by the quality assurance department as required by GMP, and external audits, which can consist of an legal audit agency, a consultant checking your compliance status, or you performing a supplier audit.

Finally, the results of audits will help you to know if you need to modify your standards of performance. No procedures should be changed without appropriate change control and approval from quality assurance (WHO, 2004). The glue that sticks the whole process together is committed. Commitment to GMP and quality is critical at all levels of the organization, starting with top management. If you foster commitment, use this process you will help you make GMP a Lifestyle, not just a regulation in the company. You will then improve the overall performance of your workforce, as well as your compliance to regulation.

2.3.7.3 Benefits of Implementation of Good Manufacturing Practices

According to Wilson (1995), implementation of quality management practices in any organization leads to synergy of benefits. Various quality management practices including good manufacturing practices provide a management system that uses a combination of tools. Good Manufacturing practices is essentially a top management slogan that when properly implement will yield enormous benefits to the organization.

A fully documented quality management practice system will ensure that two important requirements are meet. These are first and foremost the customer's requirements – confidence in the ability of the organization to deliver the desired product and service consistently meeting their needs and expectations. Secondly are customer's requirements that both internally and externally the organization uses available resources (materials, human resources, information and technology, financial resources) at an optimum cost and efficiency (Department of Trade and Industry, British Government, 2007).

A properly documented good manufacturing practices programme enables a pharmaceutical manufacturing organization to achieve the goals and objectives set out in it policy and strategy. It provides consistency and satisfaction in terms of procedures, methods, materials, equipments etc and interacts with all activities of the organization beginning with the identification of customer's requirements and ending with their satisfaction at every transaction interface. As a result of consistency achieved by implementation of good manufacturing practices, high quality medicines are available to improve public health (MSH, 1997).

2.3.7.4 Self-Inspection and Quality Audits

WHO (2004) states the purpose of self-inspection is to evaluate the manufacturers compliance with GMP in all aspects of production and quality control. The self-inspection programme should be designed to detect any shortcomings in the implementation of GMP and to recommend corrective actions. Polderman (1990) concurs and further states that self-inspections are necessary to assess adherence to GMP standards. He goes on to state that such self-inspections may be conducted by specialist from outside the organization or from other section in the same organization. He further proposed that production and quality control managers should be actively engaged in this process so that changes and improvement necessary can be implemented as soon as possible. Polderman also argues that the great majority of defective medicinal products result from human errors or carelessness but not from failures in technology.

Self-inspection should be performed routinely, and may be, in addition performed on special occasion, for example, in the case of product recalls or repeated rejections, or when an inspection by the health authority is announced. The team responsible for inspection for self-inspection should consist of personnel who can evaluate the implementation of GMP objectively. All recommendations for collective action should be implemented. The procedure for self-inspection should be documented and then there should be an effective follow-up program.

WHO (2004) proposed that items for self-inspection should be included in questionnaires on GMP requirements which will cover the following items: personnel, premises including personnel facilities, maintenance of building and equipments, storage of starting materials and finished products, equipment, production and in-process control, quality control, documentation, sanitation and hygiene, validation and devalidation programmes, calibration of instruments or measurement systems, legal procedures, complaints management, labels control, a result of previous self-inspection and any corrective steps taken.

It may be useful to supplement self-inspection with a quality audit. A quality audit consists of an examination and assessment of all or a part of a quality system with a specific purpose of improving it. A quality audit is usually conducted by outside or independent specialist or a team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors. Before suppliers are approved and included in the approved suppliers list or specifications, they should be evaluated (Reyniers et al, 1995)

MSH (1997) recommends that a suppliers' evaluation should take into account a suppliers history and the nature of the materials to be supplied. If an audit is required, it should determine the supplier's ability to conform to GMP standards.

2.3.8 Statistical Quality Techniques

Statistical process control, or SPC, is a fundamental approach to quality control and improvement that is based on objective data and analysis. The origin of PC dates back to the 1920s and 1930s at the Western Electric Company and Bell Telephone Laboratories. Walter Shewhart (1891 – 1967) recognized that variation in a production process could be understood and controlled through the use of statistical methods. He pioneered the use of statistical methods as a tool to manage and control production. Over the next several decades, these tools were taught to engineers and production personnel throughout American industry. The need for higher-quality production to support the defense industry during World War II gave a boost to the use of SPC (Chaudhry and Higbie, 1990).

One of Shewhart's disciples, Deming (1900-1993), was a strong advocate of SPC and trained many engineers in the concept during the war years. However, he was never able to convince upper management in the U.S of SPC's benefits and importance. When Deming was invited to train Japanese engineers in statistical methods after the war, he realized that quality improvement efforts could never be sustained without top management support. It was not difficult for him to gain the attention of every level of worker-from maintenance to CEO, since Japan was rebuilding from complete devastation. The Japanese were eager to learn and apply new tools that would help them rebuild their economy. And the rest, as they say, is history. Statistical methods, combined with strong programs in human resources and a focus on continuous quality improvement to better respond to customer needs, enabled Japanese companies to emerge as powerful global competitors within only a few decades (Chaudhry and Higbie, 1990).

When Deming's contributions to Japan became recognized in America around 1980, the modern quality movement began. Many major corporations began to experiment with quality improvement techniques, such as statistical process control. Ford Motor Company and other U.S. automobile manufacturers began to require their suppliers to show statistical evidence of the quality of their products as part of their Q 101 Quality System Standard. Ford insisted that statistical process control be used as an integral part

of suppliers' processes to assure quality and provide accurate information of continuous quality and productivity improvement (Chaudhry and Higbie, 1990).

Quantitative methods and statistical tools provide workers and managers with the tools needed to quantify variation, identify causes, and find solutions to reduce or remove unwanted variation, and monitor progress objectively. Statistical process control can help to achieve these goals when it is part of a total problem-solving effort. Simply going through the motions and providing data because the boss or customer wants it will not help to improve operations or better satisfy customers. Teamwork and participation play an important organizational role (James, 2006).

The term Total Quality Management is currently undergoing a transition from a traditional to more advanced interpretation. The traditional belief that companies' quality departments own quality (Hoerl, 1998) seems to be disappearing. A trend from what Juran calls the "little q" to what he terms the "Big Q" has been noted (Hoerl, 1998). In the broader "Big Q" framework, the traditional assumption that statistical quality control and improvement methods involved only the use of control charts is too narrow. Modern statistical quality control and improvement include all statistical methods (simple and complex) used to improve manufacturing as well as non-manufacturing processes (Hoerl, 1998).

In order to improve quality in all sectors of economy, it is important to realize that every process generates information that can be used for its improvement. No organization, be it public or private, manufacturing or service, should neglect the opportunity to take a close look at accumulated data as part of the operations. With this data, it is possible to discover hidden patterns in process deficiencies, form different hypothesis as to what might be the reasons for deficiencies (Hoerl, 1998).

TQM requires constant statistical measurement of quality to monitor performance. All members of an organization must become proficient in the use of statistics to the level required by the position or job. This means an organization must conduct extensive statistical training for all employees. Statistics is the science of collecting, organizing

and interpreting numerical and non-numerical facts, which we call data. The collection and study of data are important in the work of many professions, so that training in the science of statistics is valuable preparation for variety of careers, for example, economists and financial advisors, businessmen, engineers and farmers. Knowledge of probability and statistical methods also are useful for informatics' specialists of various fields such as data mining, knowledge discovery, neural network, fuzzy system and so on. Whatever else it may be, statistics is, first and foremost, a collection of tools used for converting raw data into information to help decision makers in their works (Hoerl, 1998).

When objective decisions are to be made, statistical methods should be used based on any objective information in the form of data collected about a product or process. Statistical techniques such as control charts, process capability indices and design of experiments have been used in the manufacturing industry for many years. There are a number of practical and managerial issues related to the application of statistical techniques in studies aimed at improving process and product quality. The focus should always be on continuous quality improvement using statistical techniques (Hoerl, 1998).

The success of a business depends upon the quality of the decisions it makes at each customer contact. Such decisions must reflect the business strategy, the interests of the customer, his or her value and risk to the business. In addition, because of growing customer expectations and increasing competition, businesses are under pressure to provide personalized customer service within mass market cost levels (Senn, 2002).

Decisions about customer interactions must take into account each customer's likely behavior. At each individual contact with the customer, the business must consider the relative likelihood of the customer responding to an offer, taking his or her patronage elsewhere or causing some loss to the business. The business that can determine and implement a personalized management strategy for each customer has the means of ensuring that the most suitable decisions are made in accordance with its overall objectives (Hoerl, 1998).

The pharmaceutical industry has been slow (but perhaps no slower than other industries) to implement formal decision analysis for choosing which drugs to develop and for deciding how to develop them (Senn, 1998). If we exclude pharmaceutical research and manufacturing, then the sort of areas in which the pharmaceuticals statistician might become involved are toxicology, bioassay, pharmacokinetics, the design and analysis of clinical trials, epidemiology and drug monitoring and pharmacoeconomics. Clinical trial work is by far the most important of these areas. As Lewis (1983) made clear, statisticians were already heavily involved with trial design by the early 1980s.

2.3.9 Challenges of implementing Quality Management Practices

Despite the best efforts of senior Executives, major change initiatives often fail. Those failures have at least one common root: Executives and employees see change differently. For senior managers, change means opportunity both for the business and for themselves. But for many employees, change is seen as disruptive and intrusive (Strebel, 1996).

Ideal quality management is strongly linked to managerial knowledge, as the literature suggests. Knowledgeable managers are more likely to have a good idea about how quality should be managed in the firm. Also, corporate management support for quality apparently encourages divisional managers to learn more about ideal quality management (Benson, 1991).

Raju et al (2005) contents including GMP and TQM, is critical for the success of any quality programme. When the concept of GMP becomes clear, the top management discerns how much of it is already practiced in the company and where that top management awareness and commitment to quality management practices to focus for further exercises, how much of it is manager driven and how much of it dependent on specialized tools. In their study of quality management practices, Raju and Taguchi (2005) found that the commonly experienced problems when implementing any quality improvement practice including GMP include organizational resistance to change, organizational culture bent on maintaining the status quo, lack of customer awareness on

GMP, lack of adequate resource to implement and maintain a quality assurance system, and lack of support and commitment from senior management.

The congruence of purpose in the implementation of any quality improvement programme should transcend the entire organization and even beyond. The top management has major shares of action and responsibilities to initiate and sustain improvement activities in the company. The span of quality management initiatives is not confined merely to activities within the company. It spreads beyond to outside agencies like suppliers, distributors and customers. There should be an element of commonality in the company's approach and customer's viewpoint. Although the WHO good manufacturing practices guidelines are in public domain, many pharmaceutical manufacturing companies have had extreme difficulties in implementation.

In sum, quality management practices should be viewed as an integral part of the organization's operation, not as another fad that should be briefly tolerated. This also places a crucial burden on management at all levels to provide leadership by example (McGowan, 1995).

2.4 Quality Management Practices in the Pharmaceutical Industry

In the pharmaceutical industry at large, quality management is usually defined as the aspect of management functions that determines and implements the "quality policy" i.e. the overall intention and direction of an organization regarding quality, as formally expressed and authorized by top management (WHO, 2004). Pharmaceuticals have brought tremendous health benefits to developing countries, but existing pharmaceuticals are often underused or misused and pharmaceutical R $ D on health problems specific to poor countries is woefully inadequate (Kremer, 2002). The roles of pharmaceuticals and medical technology in improving health in developing countries stand in contrast to the historical experience of the developed countries.

Pharmaceutical manufacturers compete for sales chiefly by seeking to discover and develop new drugs products and formulations (Backhaus, 1983). Prompted by concern over attempts at regulating the pharmaceutical industry on the European level, Bakchaus discusses in a study the two basic forms of regulation which we observe to be typical, quality regulation (licensing) and price regulation. He further makes an attempt to analyze regulatory behavior vis-à-vis the industry in terms of a behavioral model and an attempt is made to incorporate into the analysis the experience of quality regulation in both Europe and the United States of America (Backhaus, 1983).

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Research Design

This research project is a survey study approach for establishing quality management practices and challenges of implementation by pharmaceutical manufacturing companies. According to Kothari (2005), surveys are conducted in case of descriptive research studies, which may either be a census or sample surveys. Surveys are concerned with describing, recording, analyzing and interpreting conditions that either exist or existed. The researcher does not manipulate the variable or arrange for events to happen thus surveys are usually appropriate in case of social and behavioural sciences.

3.2 Population of the Study

The population of this study comprised of all pharmaceutical manufacturing companies in Kenya registered by the Pharmacy and Poisons Board as at 31st March 2008. This is the most current listing of pharmaceutical manufacturers operating in Kenya. There is a total of 36 companies (Appendix III) (PPB, 2008). Since the population is small, the census method was be used. Two respondents were selected from amongst employees of each pharmaceutical manufacturing company: one respondent from top-level management and one respondent from lower management.

3.3 Data Collection

Semi-structured questionnaires were used to enable the researcher obtain quantitative data from responses were analyzed in order to provide a complete picture of the quality management practices and challenges of implementation by pharmaceutical manufacturing companies in Kenya.

The questionnaire is divided into two parts. Part one captured general information about the respondents' organization, respondents' current job position and lengthy of service in that function among other information. Part two captured information in relation to quality management practices and challenges facing their implementation.

The questionnaire was administered to the respondents and collected later the following day; hence, drop - and - pick later method shall be used.

3.4 Data Analysis

The data collected was edited for accuracy, uniformity, consistency and completeness and then arranged to enable coding and tabulation before final analysis. Once collected, the data was collated, organized, summarized and described. Summary measures of central tendency (mean) and dispersion (standard deviation) were calculated, and tables and graphs created to illustrate the findings. Frequency distribution tables will be used to rank the level of entrenchment of various quality management practices to illustrate the extent of their implementation by pharmaceutical manufacturing companies. A significance test was employed to investigate significance differences between various levels of management on quality management practices. The use of the above descriptive and inferential statistics helped answer the research questions, which sought to identify quality management practices that pharmaceutical manufacturing companies in Kenya employ in the manufacture of pharmaceutical products and the challenges they face in their implementation.

CHAPTER FOUR: DATA ANALYSIS AND INTERPRETATIONS

4.1 Introduction

The study aims to identify and determine the extent of implementation of various quality management practices by pharmaceutical manufacturing companies in Kenya, and to determine the challenges of implementing quality management practices by pharmaceutical manufacturing companies in Kenya. The response rate achieved for the study is 89%. The counts were compiled manually and entered into the SPSS worksheet. Each statement in the questionnaire was rate using likert scale and averaging rating obtained, with 5 indicating strongly agree and 1 showing strongly disagree. However, for general information, each response was assigned a number to denote a specific variable. For instance, a male respondent was assigned 1 while a female one was assigned 2.

4.2 General Information

The table below (table 4.2.1) shows the responses regarding sex, department, job title and the department in which the employees have worked. The results show that most of the respondents for top management and middle level management were male, with mean values of 1.333 and 1.300 respectively. They represented 66.7% and 33.3% a frequency of 9 and 21 and respectively. In addition, most of the employees in the top management level as shown in table 4.2.1 were in granulation department (8.3667) while those in the low-level management were in the packaging department (5.4667). In terms of their job tittles, most of the top managers who responded to the responded to the study were quality control analysts (2.9333) while the low-level managers were quality control managers (1.300).

Table 4.1: General Information

		TOP MANAGEMENT				MIDDLE LEVEL MGT			
		FRQ	%	Mean	SD	FRQ	%	Mean	SD
SEX	Male	20	66.7	1.333	.47946	21	70		
	Female	10	33.7			9	30		
		30	**100**			**30**	**100**		
Department	Production	2	6.7	4.8667	2.97962	3	10	5.4667	2.86156
	Quality control	8	26.7			1	3.3		
	Tableting	4	13.3			5	16.7		
	Granulation	1	3.3			4	13.3		
	Packaging	2	6.7			4	13.3		
	Quality Assurance	4	3.3			3	10		
	Injectables	2	6.7			-	-		
	Product Development	2	6.7			-	-		
	Liquids Ointments	2	6.7			10	33.3		
	Quality Control Laboratory	3	10			-	-		
		30	**100**			**30**	**100**		
Job Title	Processor	1	3.3	8.3667	4.70131	9	30	2.9333	2.10803
	Quality Control Manager	1	3.3			7	23.3		
	Supervisor Head	6	20.0			7	23.3		
	Head of Operation	2	6.7			1	3.3		
	Packaging Supervisor	2	6.7			5	16.7		
	Production Manager	3	10			-	-		
	Quality Control Chemist	1	3.3			1	3.3		
	In-Process Quality Assurance	1	3.3			-	-		
	Head of Department	2	6.7			-	-		
	Analyst	3	10			-	-		
	Quality Control Analyst	3	10			-	-		
	HPLC Quality Control	3	10			-	-		
	Personnel	1	3.3			-	-		
	Pharmacist	1	3.3						
		310	**100**			**30**	**100**		
Number of years worked	Between 1-5	21	70	1.5000	.90019	24		1.3000	.70221
	Between 6-10	5	10.7			4			
	Between 11-15	2	6.7			1			
	More than 1 year	2	6.7			1			
		30	**100**			**30**	**100**		

Source: Research Data

4.3 The extent of implementation of various quality management

This study sought to investigate various quality management practices applied by the companies in the pharmaceutical industry. These practices tend to improve the performance of the company practicing these quality management techniques in its day-to-day activities. Increased performance will always bring about increased productivity, company performance and profitability. The respondents were asked to state to what extent you strongly agree, agree, neutral, disagree or strongly disagree with the statement made. The study was analyzed and presented under the following subheadings:

4.3.1 Top Management Commitment

Table 4.2: Top Management Commitment

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Is General management is actively involved in quality improvement?	4.0000	1.11417	3.4333	1.25075
Does Management provide the necessary resources to carry out activities efficiently?	3.5333	.97320	3.3000	1.11880
Does General management encourage employees to consider customers' needs and expectations?	3.3667	.99943	3.5000	1.30648
Does Management quality objectives are disseminated to all employees?	3.1667	.94989	3.1667	1.26173
Does the Top management pursue long-term objectives?	3.5000	1.10641	3.3333	1.39786

Source: Research Data

In relation to top commitment by top management in ensuring there is quality improvement in the firm, the total counts agree (both strongly agree and agree) was 25 (table 4.2 above). This makes a mean of 3.000 of the total counts, which indicate that management, is actively involved in quality improvement. This when compared to lower

level management, the total count strongly agreeing were only 6. Summarily, all the variables averaged above 3 in both levels of management. This indicates that top management supports quality improvement management. However, both respondents agreed that management pursues long-term objectives as shown by a mean of 3.1667 and a standard deviation of 1.10641 and 1.39786 respectively.

4.3.2 Organization for Quality

Table 4.3: Organization for Quality

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Does the organization have a process management method?	3.4167	.71728	3.2333	1.2287
Are Interdepartmental groups are common?	3.5000	.88465	2.8667	1.25212
Are the processes are continuously improved?	3.5833	.92861	3.3000	1.26355
Does the organization use quality circles?	3.1250	.79241	3.3000	1.26355
Is there is little bureaucracy (formal hierarchy, procedures and detailed rules) in the organization?	3.1250	1.03472	3.0667	1.36289

Source : ***Research Data***

In relation to organization for quality, top management scored a mean above 3 in all the variables. This shows that the respondents believe that in their pharmaceutical firms, they agree that there are organizations for quality. However, the presence interdepartmental groups scored a mean of 2.8667. This indicates that not all pharmaceutical firms have continually encouraged quality as apart of the entire organization's activities as shown in table 4.3 above.

4.3.3 Employees Training

Table 4.4: Employee Training

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Does the company provide continuous training for its managerial personnel?	3.2333	1.19434	3.5333	1.22428
Does the company provide continuous training for its non-managerial personnel?	2.8333	1.26173	3.4333	1.35655
Does training needs are always evaluated?	3.0333	1.06620	3.4000	1.16264
Do employees take training leave?	2.2667	1.14269	2.7333	1.25762
Does the company measures employee satisfaction with training received?	2.2000	1.27035	2.8667	1.35752

Source: ***Research Data***

The researcher asked the respondents question relating to employee training. All the responses given by the top management indicates they agree with their efforts in providing training to the employees. As sown in table 4.4 above, the responses averaged 3. However, the lower level management's responses varied ranging from disagreeing to agreeing as their means ranged from 2 to 4. Furthermore, the disagreement was mostly on the aspect of whether employees can take training leave. The response was that they agreed (2.7333).

4.3.4 Employee Participation

Table 4.5: Employee Participation

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Does the company provide continuous training for its managerial personnel?	3.0333	1.15917	3.7000	1.23596
Does the company provide continuous training for its non-managerial personnel?	2.8000	1.15669	3.3667	1.24522
Are training needs are always evaluated?	3.1333	1.25212	3.4667	1.27937
Can employees take training leave?	3.3667	1.03335	3.2667	1.36289
Does the company measure employee satisfaction with training received?	4.0333	.99943	3.8333	1.17688
Are there are work related meetings with colleagues.	2.8667	1.47939	2.6667	1.37297

Source: ***Research Data***

When the researcher asked the two groups of management, on the level of participation by employees in quality management, they all agreed as shown in table 4.5 that they participate in managing quality. The responses except one averaged above 3 indicating that there was an agreement as to the participation of employees in quality improvement. However both teams disagreed that the there were frequent work related meetings with colleagues.

4.3.5 Supplier Quality Management

Table 4.6: Quality System Improvement

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Does the company purchases raw materials only from qualified suppliers?	2.9000	1.34805	3.6000	1.36443
Does the company work in close collaboration with suppliers to improve processes?	3.0607	1.46059	3.5667	1.22287
Does the company supplies technical assistance to suppliers?	3.0333	1.27267	2.9667	1.06620
Is the company in partnering with its suppliers?	2.8010	.96132	2.9333	.98027
Does the company has few customers	2.7000	1.29055	2.9667	1.15917

Source :*Research Data*

The above results show that on average there is a consensus that there is a supplier quality management. It is also interesting to note as shown in table 4.6 that the pharmaceutical firms sampled have fewer suppliers. This in a sense means that they are able to monitor quality of their products very easily.

4.3.6 Customer Focus

Table 4.7: *Customer Focus*

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Is the client is integrated in the product development process?	2.7917	1.10253	3.2000	1.15669
Does company carry out studies to evaluate customer satisfaction?	3.0417	.85867	3.2333	1.19434
Does company carry out market studies to determine its customers' needs and wants?	3.1250	.79741	3.3667	1.32570
Does the company has a system to collect customers' complaints?	3.4830	.93153	3.4000	1.03724
Are corrective actions always taken to address customer complains?	3.7917	.72106	3.3000	1.23596
Are all expectations of your external customers are met?	2.9983	1.0417	3.1333	1.22428
What is the frequency of meeting with external customers	3.1667	1.20386	2.8000	1.37365

Source: ***Research Data***

The average responses of both the top and middle-level management is achieved as per customer focus was 3. However, middle-level management showed a stronger response an indication that confirms that they are in frequent contact with the customers. The results show that lower level managers understands that leading customer service leads to customer satisfaction, and internal customer service will lead to employee satisfaction. Such results show that lower employees also understands that internal customer service is the service we provide to fellow employees and other departments within our own organizations, as well as our suppliers and anyone else with whom we work to get our jobs done.

4.3.7 Quality System Improvement

Table 4.8: Quality System Improvement

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Are there are frequent meetings with external customers?	3.6667	1.21296	3.13333	1.30604
Does the company has a clear quality manual?	3.2667	1.17248	3.60000	1.32573
Is the Quality system in our company is improved continuously?	4.1000	.92289	3.6000	1.35443
Does company has a clear documentation procedure?	3.8333	1.11675	3.7333	1.14269
Does the company have a clear set of work instructions?	3.7667	1.10433	3.7000	1.3933
Are there company's clear standard operating procedures (SOPs) which are clearly understood by operating staff?	3.6333	1.09807	3.5667	1.38174
Are employees are encouraged to apply better methods when doing work after learning new skills?	2.7667	1.42527	2.8607	1.40770
Are there are frequent self-inspection and quality audits exercises in the company?	2.8667	1.52527	2.9607	1.41270

Source: ***Research Data***

In relation to system quality improvement, there is a consensus by both levels of management that the companies that they have clear quality manual, clear documentation of work instructions, as well as encouraging better methods of doing work after learning better new better skills. The results show that top management has a mean of more than 3 than the lower management whose ranges from 2 to 3 (see table 4.8 above). However, as regards to frequent self-inspection and quality audit exercises in the companies, both groups disagree in that context hence there should be improvement.

4.3.8 Statistical Quality Techniques

Table 4.9: Statistical Quality Technique

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Are cards and graphs are used to measure and control quality?	3.3333	.39786	3.1333	1.13664
Does the general management encourage the use of statistical methods?	3.3333	1.26854	3.4000	1.27577
Are statistical techniques used intensively in the company?	2.9333	1.41259	3.6000	1.00344
Do employees participate in training programs related to statistical techniques for quality?	2.5000	1.41259	3.4667	1.3604
Are the statistical techniques effective at improving product quality?	3.5000	1.25238	3.7000	.91339
Are statistical techniques used for product release?	3.2333	1.19434	3.2333	.13512
Acceptance sampling is applied to determine acceptance or rejection of all materials used for manufacturing?	2.5667	1.16511	2.7333	1.25762
Are control charts used to determine if variations are abnormal or normal and to determine quality characteristics?	2.6000	1.16511	2.7333	1.31131
Are predetermined raw materials specifications and finished products specifications used in manufacturer and products release?	3.1607	1.20583	3.0000	1.33907

Source: ***Research Data***

In terms of use of statistical tools in, most of the respondents in both groups indicate that they are neutral except for a few who strongly believe the tools are effective in quality management. This could be attributed to the variations in their fields of specialization as shown by as shown in table 4.9 above whose means are marginally above 3. This shows that in the pharmaceutical firms sampled they fail to recognize that a fully documented quality management practice system will ensure that customer's requirements both internally and externally are met.

4.3.9: Challenges of Implementing Quality Management Practices

Table 4.10: Challenges of Implementing Quality Management Practices

	TOP MGT		MIDDLE LEVEL MGT	
	MEAN	SD	MEAN	SD
Is there is congruency of purpose between management and non-management employees?	3.3333	.21296	8.2333	1.13512
Is the implementing quality management practices is the responsibility of all employees of the organization.	2.6667	.99424	3.0000	.14470
There are adequate resources to implement quality management practices?	2.8333	1.28877	2.8000	1.37465
Are there rewards for implementing quality management across the entire organization?	3.3333	1.15470	3.4333	.97143
Is there a synergy between continuous improvement approaches in my department and other departments in the organization?	2.5000	1.00858	3.3667	1.15917
Is everyone in the organization understands quality management practices and are supportive of continuous improvement initiatives?	2.8667	1.16658	3.2667	.94443
Are there higher costs of compliance to quality management practices?	3.0667	1.11211	3.5667	1.16511
Is there a difficulty in getting competent suppliers?	3.0667	1.22990	3.3000	1.02217
Is there organization-wide focus towards continuous improvement?	2.6667	.29544	3.0667	1.43679
Is there a clear monitoring and evaluation criteria for improvements made?	2.4333	1.30472	3.0333	1.37674
Is there a clear direction on how to use information gained to improve product design and customer service?	2.7333	1.28475	3.0000	1.20344

Source: ***Research Data***

The above results indicate that though there is a progress as far as quality improvement is concerned, some challenges exist. For instance, top management-rewarding employees on continuous improvement. With lower level management, they scored the highest mean of 8.2333 on whether there is there is congruency of purpose between management and non-management employees. This surprisingly is in contrast with what the management thinks (a mean of 3.333 as shown in table 4.10 above.

CHAPTER FIVE: CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

5.1 Introduction

This chapter presents the conclusions, recommendations, limitations and suggestion for further research for the study. The chapter summarizes the findings of the study in relation to the objectives of the study. The first objective was to identify and determine the extent of implementation of various quality management practices by pharmaceutical manufacturing companies in Kenya. The second objective was to determine the challenges of implementing quality management practices by pharmaceutical manufacturing companies in Kenya.

5.2 Summary

This study sought to investigate various quality management practices applied by the companies in the pharmaceutical industry. The results supports the literature that the process by which top managers allocates their limited attention among a wide variety of potential strategic issues is critical to understanding organizational adaptation and change (Dutton, 1988). In addition, the results scored a mean of more than 3 which indicates that this result is in line with literature put forward by Berman et al (1995). They have shown that executive culture and top management leadership are significant determinants of quality management commitment and impact.

Process management is a way, in which an individual, a group, a project, or an organization thinks about, and managers, its work activities. It is based on the following process management premise: the quality of the product is governed primarily by the quality of the process used (Shapiro, 1995). The results in relation to organization for quality, top management scored a mean above 3 in all the variables. This shows that the respondents believe that in their pharmaceutical firms, they agree that there are organizations for quality. However, the presence interdepartmental groups scored a mean

of 2.8667. This indicates that not all pharmaceutical firms have continually encouraged quality as apart of the entire organization's activities as shown in table 4.3 above.

The researcher asked the respondents question relating to employee training. All the responses given by the top management indicates they agree with their efforts in providing training to the employees. As shown in table 4.2 above, the responses averaged 3. However, the lower level management's responses varied ranging from disagreeing to agreeing as their means ranged from 2 to 4. Furthermore, the disagreement was mostly on the aspect of whether employees can take training leave. The response was that they agreed (2.7333). It has become a widely held premise that people provide organizations with an important source of sustainable competitive advantage and that the effective management of human capital, not physical capital, may be the ultimate determinant of organizational performance (Adler, 1988; Reich, 1991). Given the team-based problem-solving nature of total quality management programs, firms adopting a quality strategy must facilitate employee interaction and information exchange (Youndt et al, 1996). The value of human capital may be especially apparent in modern, manufacturing organizations that have invested heavily in production innovations such as advanced manufacturing technology, statistical process control and computer numerically controlled machine tools. Such initiatives tend to depend heavily on employee skills and commitment as key components in the value creation process (Snell, 1992). The results therefore particularly for the lower management contradicts this wide held believe that there should be congruence between team-based problem solving and individual innovation.

Employee participation is any quality improvement initiative is critical for its success. Several authors have identified employee empowerment, formation of quality circles and employee fulfillment as critical ingredients for successful employee participation in quality management practices. When the researcher asked the two groups of management, on the level of participation by employees in quality management, they all agreed as shown in table 4.5 above that they participate in managing quality. The responses except one averaged above 3 indicating that there was an agreement as to the

participation of employees in quality improvement. However both teams disagreed that the there were frequent work related meetings with colleagues. This is an indication that there is lack of bottom-up communication which is very dangerous for pharmaceuticals which are operating in such a competitive environment.

A central theme of quality management is that technical and human aspects of a process must be managed in concert. Complementing the design of efficacious development processes, work design practices that foster participation of key stakeholders and empowerment of employees need to be established (Ravichandran & Rai, 2000). The respondents indicated that on average there is a consensus that there is a supplier quality management and that the pharmaceutical firms sampled have fewer suppliers. This in a sense means that they are able to monitor quality of their products very easily. In addition, this shows that the firms have attempted to use improved quality to gain a competitive advantage in developing quality-sensitive industrial contracts.

Internal customer focus is a key ingredient quality management practices. However, Lewis (1989) points out that emphasizing focus is one thing; delivering it is another. In fact, he considers that emphasizing focus is not most appropriate approach to adopt. Thus management policies that enhance internal customer-based focus often prove to be a firm's best marketing strategy. Christopher et al (1991) go further than this to describe a new relationship between quality, customer service and marketing. They argue that quality is also a key linkage in the exchange relationship between the organization and its employees as customers. They maintain that unless management can bring these activities together with new forms of collaboration and cross-functional coordination, there can be no sustainable competitive advantage.

On customer focus the lower level management who deal directly with the customers indicated that they are in constant contact with external customers. This supports the literature that firms should weaken the tendency to build territorial walls and adopt ways of creating forums to share information, practice proactive information-sharing and create or contribute to, an environment in which status is accorded to those who share freely and

not to build walls (Buzzell, 1987). As a result of this, customer service will lead to customer satisfaction and hence employee satisfaction.

In relation to system quality improvement, there is a consensus by both levels of management that the companies that they have clear quality manual, clear documentation of work instructions, as well as encouraging better methods of doing work after learning better new better skills. The results show that top management has a mean of more than 3 than the lower management whose ranges from 2 to 3 (see table 4.8). However, as regards to frequent self-inspection and quality audit exercises in the companies, both groups disagree in that context hence there should be improvement.

In terms of use of statistical tools in, most of the respondents in both groups indicate that they are neutral except for a few who strongly believe the tools are effective in quality management. This could be attributed to the variations in their fields of specialization as shown by as shown in table 4.9 above whose means are marginally above 3. This shows that in the pharmaceutical firms sampled they fail to recognize that a fully documented quality management practice system will ensure that customer's requirements both internally and externally are met. A properly documented good manufacturing practices programme enables a pharmaceutical manufacturing organization to achieve the goals and objectives set out in it policy and strategy. It provides consistency and satisfaction in terms of procedures, methods, materials, equipments etc and interacts with all activities of the organization beginning with the identification of customer's requirements and ending with their satisfaction at every transaction interface. As a result of consistency achieved by implementation of good manufacturing practices, high quality medicines are available to improve public health (MSH, 1997).

In relation to challenges that management faces in implementing quality management practices the results indicate that though there is a progress as far as quality improvement is concerned, some challenges exist. For instance, top management-rewarding employees on continuous improvement. The lower level management, scored the highest mean of 8.2333 on whether there is there is congruency of purpose between management and non-management employees. This surprisingly is in contrast with what the management

thinks (a mean of 3.333 as shown in table 4.10 above. This indicates that without full support fro the top level management, the lower management cannot implement quality management systems. The congruence of purpose in the implementation of any quality improvement programme should transcend the entire organization and even beyond. The top management has major shares of action and responsibilities to initiate and sustain improvement activities in the company. The span of quality management initiatives is not confined merely to activities within the company. It spreads beyond to outside agencies like suppliers, distributors and customers. There should be an element of commonality in the company's approach and customer's viewpoint. In sum, quality management practices should be viewed as an integral part of the organization's operation, not as another fad that should be briefly tolerated. This also places a crucial burden on management at all levels to provide leadership by example (McGowan, 1995).

5.3 Conclusion

This study revealed the importance pharmaceutical firms attach to quality improvement. The study also revealed that the basic elements of quality management such as an appropriate infrastructure or quality system encompassing the organizational structure, procedures, process and resources; systematic action necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality are indeed vital for any quality management activity. In relation to top commitment by top management in ensuring there is quality improvement in the firm, the total counts agree (both strongly agree and agree) was 25. This make 83.3% off the total counts, which indicate that management, is actively involved in quality improvement. This when compared to lower level management, the total count strongly agreeing were only 6. Summarily, all the variables averaged above 3 in both levels of management. This indicates that top management supports quality improvement management. From top-level administrators to front-line managers, quality management practices have permeated the entire pharmaceutical industry.

Total quality management significantly alters the way jobs are designed requiring new behaviors, roles and responsibilities for all organizational members (Koike, 1988). This is supported by the results of the study which show that the two groups of management, on the level of participation by employees in quality management, they all agreed that they participate in managing quality. The responses except one averaged above 3 indicating that there was an agreement as to the participation of employees in quality improvement. However both teams disagreed that the there were frequent work related meetings with colleagues.

5.4 Recommendations

Given the team-based problem-solving nature of total quality management programs, firms adopting a quality strategy must facilitate employee interaction and information exchange (Youndt et al, 1996). Therefore, pharmaceutical firms must ensure that frequent work related meetings with colleague are encouraged. In line with statistical tools for managing quality, the value of human capital may be especially apparent in pharmaceutical firms that have invested heavily in production innovations such as statistical process control and computer numerically controlled machine tools. Such initiatives tend to depend heavily on employee skills and commitment as key components in the value creation process (Snell, 1992). The study showed that of the respondents in both groups indicates that they are neutral except for a few who strongly believe the tools are effective in quality management. This could be attributed to the variations is their fields of specialization.

5.5 Limitations of the study

This research project was a survey study approach for establishing quality management practices and challenges of implementation by pharmaceutical manufacturing companies in Kenya. It is recommended that a similar study could be replicated by studying two sets of firms, those that have won ISO Certification on quality improvement and those, which have not met the ISO quality award standard.

5.6 Suggestions for Further Study

The results show that respondents believe that in their pharmaceutical firms, they agree that there are organizations for quality. However, the presence interdepartmental groups indicating that not all pharmaceutical firms have continually encouraged quality as apart of the entire organization's activities. Therefore the researcher recommends that a study be carried out to ascertain why there is the presence of interpersonal groups.

It is further recommended that a study to determine why both top and middle level management disagreed that there were frequent work related meetings with colleagues.

Another area for further study is determining why all the responses given by the top management indicates they agree with their efforts in providing training to the employees while lower level management responses varied ranging from disagreeing to agreeing mostly on the aspect of whether employees can take training level.

Finally, another research can carried out in different regions in the country and make a comparison of the results in order to check whether quality management are carried by all managers operating pharmaceutical firms in Kenya.

REFERENCES

Aragon et al (1993) "Evaluating the Deming Management Model of Total Quality in Services," *Decision Sciences*, p.1.

Adam Everelt Jr. and Ebert J. Ronald (2001) *Production and Operations Management Concepts, Models and Behaviour.* Asoke K. Ghosh, Prentice Hall of Inida Private Limited: India.

Alder, P. S. (1988) Managing Flexible Automation, *Califonia Management Review*, Vol.30(3), pp.34-56.

Anderson, J., Rungtusanathan, M. and Schroeder, R (1994) "A Theory of Quality Management Underlying the Demining Management Method," *Academy of Management Review*, Vol.19, No.3, pp.472-509.

Anderson, M. and Sohal, A. S. (1999) "A Study of the Relationship between Quality Management Practices and Performance in Small Business" *International Journal of Quality and Reliability Management*, Vol.16, No.9.

Application Guidelines Malcolm Baldige National Quality Award (1991), *US Department of Commerce, National Institute of Standards and Technology*, Gaithersburg, MD.

Arthur, J. B. (1992) "The Link between Business Strategy and Industrial Relations Systems in American Steel Minimills" *Industrial and labour Relations Review*, Vol.45, plp.488-506.

Backhaus, J. (1983) "Competition, Innovation and Regulation in the Pharmaceutical Industry," *Managerial and Decision Economics*, Vol.4, No.2, pp.107-121.

Banker, R. D., Field, J. M., Schroeder, R. G., Sinha, K. K. (1996) "Impact of Work Teams on Manufacturing Performance: A Longitudinal Field Study," *The Academy of Management Journal*, Vol.39, No.4, pp.867-890.

Bennis and Nanus (1985) *Making Total Quality Management: Quality Tools for Human Service Organizations*. New York: Springer Publishing Company.

Benson, P. G., Saraph, J. V. and Scheroeder, R. G. (1991) "The Effects of Organizational Context on Quality Management: An Empirical Investigation" *Management Science*, Vol.37, No.9, pp.1107 – 1124.

Berman, E. M., West J. P. (1995) "Total Quality Management in American Cities: Hypothesis Regarding Commitment and Impact. *Journal of Public Administration Research and Theory, J-PART*, Vol.5, No.2, pp.213-230.

Best, M. H. (1990) *The New Competition: Institutions of Industrial Restructuring*. Harvard University Press, Cambridge, M.A.

Buzzell, R. and Gale, B. (1987) *The PIMS Principles: Linking Strategy to Performance*. New York: Free Press.

Chaundry and Higbie (1990) The Application of Total Quality Management Tools in a Strategic Business Plan, *Centre for Quality of Management Journal*, 8(3).

Chew, W. B. and Pisano (1990) "Vertical Integration, Long-term Contracts and the Cost of Quality," Harvard Business School Working Paper.

Cole, R. E. (1980) *Work, Mobility and Participation: A Comparative Study of America and Japanese Industry*. Berkeley, Calif; University of California Press.

Conger and Kanungo (1989) Integration of Climate and Leadership: Examination of Neglected Issue. *Journal of Applied Psychology*.

Connell and Ryan (1989) *"Conducting Quality Survey,"* Concordia University, Page 1 – 29.

Crosby B. Philip and Ivancevich M. John (1997) *Management: Quality and Competitiveness*, 2nd edition. Irwin McGraw Hill: Boston.

David A. Garvin (1987) "Competing on the Eight Dimensions of Quality," Harvard Business Review, November - December, pp.101-109.

Dean, J. W. and Bowen, D. E. (1994) "Management Theory and Total Quality Management: Improving Research and Practice through Theory Development", *Academy of Management Review*, Vol.19 No.3, pp.392-418.

Department of Trade and Industry (2007)website: www.dti.gov.uk/quality/implementation, on 28th February 2008.

Dobbs, F. Matti (1994) "Continuous Improvement as Continuous Implementation: Implementing Total Quality Management in the City of Santa Ana" *Public Productivity and Management Review*, Vol.18, No.1, pp.89-100.

Dutton, J. E. (1988) Understanding Strategic Agenda Building and its Implications for Management Change. In L.R. Pondy, R. J. Boland and H. Thomas (Eds), *Managing Change and Ambiguity:* 127-144, Chichester, England; Wiley.

Dwyer, R. F. (1993) *"Soft and Hard Features of Interfirm Relationships: An Empirical Study of Bilateral Governance in Industrial Distribution*" Report 6. University Park PA: Institute for the Study of Business Markets.

Edwards Deming (1982) *Out of the Crisis*. Cambridge: Mass: MIT Centre for Advanced Engineering Study.

Emshwiller, J. R. (1991) "Suppliers Struggle to Improve Quality as Big Firms Slash Their Vendor Rolls," *Wall Street Journal* (August 16), B1 – B2.

Flynn, B. B., Sakakibara, S., Schroeder, R. G. (1995) "Relationship Between Just-In-Time and Total Quality Management Practices and Performance," *The Academy of Management Journal*, Vol.38, No.5, pp.1325-1360.

Fredrick M. Garfield (1985) *Quality Assurance Principles for Analytical Laboratories*. Association of Official Analytical Chemists: USA.

Greene, R. T. (1993) *Global Quality: A Synthesis of the World's Best Management Methods*. ASQC Quality Press and Business One, Irwin, Milwaukee.

Griffin, R. W. (1988) "A Longitudinal Assessment of the Consequences of Quality Circles in an Industrial Setting", *Academic Management Journal*, Vo.31(2), pp.338-358.

Gronroos et al (1979) Relationship of Age and Seniority with Career Variables of Engineers and Scientists, *Journal of Applied Psychology*, 56, 388-396.

Hackman & Oldham (1975) "Employee Involvement and Participation – Human Resources Sustainability and High Involvement Management," *London School of Economics, Department of Industrial Relations*, p.4.

Hawkins, D. M. (1993) Regression Adjustment for Variables in Multivariate Quality Control Journal. *Quality Tech.* Vol.25, pp.170-182.

Impact of Current Good Manufacturing Practices and Emission Regulations and Guidance on the Discharge of Pharmaceutical Chemicals into the Environment from Manufacturing Use and Disposal *Environmental Health Perspectives*, Vol.110, No.3, pp.213-220.

Hoerl, Boer, H. and James, R. E. (2001) "Knowledge and Continuous Innovation,": *The CIMA Methodology, International Journal of Operations and Production Management*, Vol.21, No.4, pp.490-530.

Koike, K. (1988) *Understanding Industrial Relations in Modern Japan*. MacMillan, Basingstoke, England.

Kothari, C. R. (2004) *Research Methodology: Methods and Techniques*, 2nd edition. New Age International Publishers; New York.

Kotler, P. (1967) *Marketing Management Analysis, Planning and Control*, 9th ed. Prentice Hall Inc. Englewood Cliffs, New York.

Kremer, M. (2002) "Pharmaceuticals and the Developing World," *The Journal of Economic Perspectives,* Vol.16, No.4, pp.67-90.

Kremer, M. (2002) "Pharmaceuticals and the Developing World". *The Journal of Economic Perspectives,* Vol.16, No.4, pp.67-90.

Lakhal, L., Pasin, F., Liman, M. (2005) Quality Management Practices and Their Impact on Performance www.emeraldmsight.com/0265-671x.htm

Lall, S. (1985) *Appropriate Pharmaceutical Policies in Developing Countries: Managerial and Decision Economics*, Vol.6, No.4, pp.226-233.

Lee Krajewski & Larry Ritzman (1998) *Operations Management*, 5th edition. Addison Wesley Longman: USA

Lewis, J. A. (1983) "Clinical Trials: Statistical Development of Practical Benefit to the Pharmaceutical Industry (with discussion)," *J. R. Statistical Society A.,* 146: 362-393.

Management Sciences for Health (1997) *Managing Drug Supply.* Kumariam Press: Connecticut: USA.

Mark Z. Tabladillo and Gillan (1997) *"Quality Management Climate Assessment in Healthcare,"* Georgia Institute of Technology, p.40.

Martinez-Lorente, A. R., Dewhorst, F. and Dale, B. G. (1998) "Total Quality Management: Origins and Evolution of the Term," *Total Quality Management Magazine*, Vol.10, No.5, pp.378-386.

McGowan, R. P. (1995) "Total Quality Management: Lessons from Business and Government" *Public Productivity and Management Review*, Vol.18, No.4, pp.321-331.

Meredith J. R. (1992) The Management of Operations: A Comparative Emphasis.

Ministry of Health (1994) *Kenya's Health Policy Framework.*

Ministry of Health (2007) *Kenya National Pharmaceutical Policy.*

Monden, Y. (1983) *Toyota Production Systems: Practical Approach to Production Management.* Institute of Industrial Engineers, Norcross, G.A.

Monden,Y. (1989) *JIT Production System for Auto Industrial.* Japan Productivity Centre, Tokyo.

Musau, J. M. (2003) *Continuous Improvement Climate Survey at Colgate-Palmolive Kenya*, Unpublished MBA Project, University of Nairobi.

Mwihaki, N. (2005) *Effects of ISO Certification on Operation Performance: The Case of Johnson Diversey*, Unpublished MBA Project, University of Nairobi.

O'Neal, C. R. (1989) "Just-In-Time Procurement and Relationship Marketing" *Industrial Marketing Management*, Vol.18, pp.55-63.

Organ, D. W. (1988) *Organizational Citizenship Behaviour: The Good Soldier Syndrome*. Lexington, M.A.; Lexington Books.
Pharmacy and Poisons Board (2008) www.ppb.co.ke

Polderman J. (1990) *Introduction to Pharmaceutical Production.* Novib: Netherlands.

Powell, C. (1995) "Total Quality Management as Competitive Advantage: A Review and Empirical Study", *Strategic Management Journal*, Vol.16, No.1, pp.15-37.

Rahman, S. and Bullock, P. (2002) "Soft TQM hard TQM and Organizational Performance Relationships: An Empirical Investigation" Omega, Vol.33, No.1, pp.73-83.

Ravichandram, T., Rai, A. (2000) "Quality Management in Systems Development: An Organizational System Perspective", *MIS Quarterly*, Vol.24, No.3, pp.381-415.

Reeves, C. A., Bednar, D. A. (1994) Defining Quality: Alternatives and Implications. *The Academy of Management Review*, Vol.19, No.3, Special Issue "Total Quality" pp.419-445.

Reich, R. B. (1991) *The Work of Nations: Preparing Ourselves for 21st Century Capitalism.* New York, Knopf.

Reyniers, D. J., Tapiero, C. S. (1995) "The Delivery and Control of Quality in Supplier – Producer Contracts," *Management Science*, Vol.41, No.10, pp.1581-1589.

Robbins et al (2002) "The Effects of Continuous Improvement and Innovation Management Practice on Small to Medium Enterprise (SME) Performance," European Australian Cooperation Centre, Faculty of Economics and Commerce, University of Melbourne, pg.3-4.

Saraph, J. V., Benson, P. G. and Schroeder, R. G. (1989) "An Instrument for Measuring the Critical Factors of Quality Management, Vol.19, No.17, pp.902-70.

Senn, S. J. (1997) *Statistical Issues in Drug Development*, Ghichester, Willey Lancet, 352, 85 – 86.

Senn, S. J. (2000) "Consensus and Controversy in Pharmaceutical Statistics" *The Statistician*, Vol.49, No.2, pp.135 – 176.

Shapiro, C. (1995) "*Total Quality Management Journal,*" TKD Tutorage, Vol.1, No.1, pp.1-14.

Shelty, Y. K. (1992) "A Point of View: Seven Principles of Quality Leaders", *National Productivity Review*, 1991 – 1992, Vol.11, p.1.

Snell, S. A. (1992) Control Theory in Strategic Human Resource Management: The Mediating Effect of Administrative Information. *Academy of Management Journal*, Vol.35, pp.467-504.

Stevenson William, J. (2002) *Operations Management*, 7th Edition. Mc-Graw Hill: New York.

Strebel, P. (1996) Why Do Employees Resist Change, *Journal of Management Review*, Vol.18, pp.125-133.

Sundara Rahu (1995) *Total Quality Management.* Tata McGraw-Hill Publisher: New Delhi.

Thomas and Velthouse (1990) *"Organizational Commitment, Job Redesign, Employee Empowerment and Intent to Quit Among Survivors of Restructuring and Downsizing"* Institute of Behavioural and Applied Management, North Carolina A & T State University.

Victor, B. Boynton, A., Stephens-Jahng, T. (2000) The Effective Design of Work Under Total Quality Management" *Organization Science*, Vol.11, No.1, pp.102-117.

Waldman, D. A (1994) "The Contribution of TQM to a Theory of Work Performance Academy of Management Review, Vol.19, No.3.

White, J. E., Pearson, J. N., Wilson, J. R. (1999) "Just-In-Time Manufacturing: A Survey of Implementations in Small and Large U.S. Manufacturers," *Management Science*, Vol.45, No.1, pp.1-15.

World Health Organization (2004) *"Quality Assurance of Pharmaceuticals: A Compendium of Guidance and related Materials,"* Geneva.

Youndt, M. Snell, S. A., Dean J. W.; Lepak D. P. Human Resource Management, Manufacturing Strategy and Firm Performance, *The Academy of Management Journal*, Vol.39, No.4, pp.36-866.

Zanlek, P. F., Wright, G. P., Plante, R. D. (2002) "Process and Product Improvement in Manufacturing Systems with Correlated Stages" *Management Science*, Vol.48, No.5, pp.591-606.

APPENDICES

APPENDIX 1: INTRODUCTION LETTER

Dear Sir / Madam,

This questionnaire is designed to help carryout a survey of quality management practices in the pharmaceutical manufacturing companies in Kenya. This is for the purpose of analyzing the perception of employees of the company on the fundamental areas of quality management practices.

I wish to request that you respond to the questions sincerely. I wish to assure you that your responses will be held in confidence. It is only I, the researcher and the project supervisor who will have access to the information given. I will ensure that upon request, the summary of the results is made to you after the information collected is duly analyzed.

I wish to thank you very much not only for your valuable time but also co-operation. My appreciation goes to you and your organization in helping me in my research endeavours.

Yours sincerely,

Paul K. Tanui
(Student)

S. O. Nyamwange
Lecturer/Supervisor
Department of Management Science
University of Nairobi

APPENDIX II: QUESTIONNAIRE

Part A: General Information

1. Employee name (optional) _____
2. Sex (tick appropriately) Male [ ] Female[ ]
3. Name of the Company (optional) _____
4. Department _____
5. Job title _____
6. Number of years worked in the company _____ years

Part B

The following statements relate to quality management practices by pharmaceutical manufacturing companies.

Mark appropriately with X in spaces provided in the table, which signify to what extent you strongly agree, agree, neutral, disagree or strongly disagree with the statement made.

		Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
1.	General management is actively involved in quality improvement.					
2.	Management provides the necessary resources to carry out activities efficiently.					
3.	General management encourages employees to consider customers' needs and expectations.					
4.	Management quality objectives are disseminated to all employees.					
5.	Top management pursues long-term objectives.					
6.	The organization has a process management method.					

Continued

		Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
7.	Interdepartmental groups are common.					
8.	Processes are continuously improved.					
9.	The organization uses quality circles.					
10.	There is little bureaucracy (formal hierarchy, procedures and detailed rules) in the organization.					
11.	The company provides continuous training for its managerial personnel.					
12.	The company provides continuous training for its non-managerial personnel.					
13.	Training needs are always evaluated.					
14.	Employees can take training leave.					
15.	The company measures employee satisfaction with training received.					
16.	There are frequent Good Manufacturing Practices (GMP) training sessions for operating staff.					
17.	Employees are encouraged to be totally involved in issues of quality management practices.					
18.	Management lets employees participate in achieving organizational objectives.					
19	Employees are responsible for the tasks they perform, and inspect their own work.					
20	Supervisors respect the work related opinion of their subordinates.					
21.	Employees cooperate with their colleagues to work in teams.					
22.	There are frequent work related meetings with colleagues.					
23.	The company purchases raw materials only from qualified suppliers.					
24.	The company works in close collaboration with suppliers to improve processes.					
25.	The company supplies technical assistance to suppliers.					
26.	The company is partnering with its suppliers.					

Continued

		Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
27.	The company has few suppliers.					
28.	Client is integrated in the product development process.					
29.	Company carries out studies to evaluate customer satisfaction.					
30.	Company carries out market studies to determine its customers' needs and wants.					
31.	Company has a system to collect customers' complaints.					
32.	Corrective actions are always taken to address customer complains.					
33.	All expectations of our external customers are met.					
34.	There are frequent meetings with external customers.					
35.	Company has a clear quality manual.					
36.	Quality system in our company is improved continuously.					
37.	Company has a clear documentation procedure.					
38.	Company has a clear set of work instructions.					
39.	The company has clear standard operating procedures (SOPs) which are clearly understood by operating staff.					
40.	Employees are encouraged to apply better methods when doing work after learning new skills.					
41.	There are frequent self-inspection and quality audits exercises in the company.					
42.	Cards and graphs are used to measure and control quality.					
43.	General management encourages the use of statistical methods.					
44.	Statistical techniques are used intensively in the company.					
45.	Employees participate in training programs related to statistical techniques for quality.					
46.	Statistical techniques are effective at improving product quality.					

Continued

		Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
47.	Statistical techniques are used for product release.					
48.	Acceptance sampling is applied to determine acceptance or rejection of all materials used for manufacturing.					
49.	Control charts are used to determine if variations are abnormal or normal and to determine quality characteristics.					
50.	Predetermined raw materials specifications and finished products specifications are used in manufacturer and products release.					
51.	We have a forum to address challenges we face in implementation of quality management practices.					
52.	There is congruency of purpose between management and non-management employees.					
53.	Implementing quality management practices is the responsibility of all employees of the organization.					
54.	There are adequate resources to implement quality management practices.					
55.	There are rewards for implementing quality management across the entire organization.					
56.	There is synergy between continuous improvement approaches in my department and other departments in the organization.					
57.	Everyone in the organization understands quality management practices and are supportive of continuous improvement initiatives					
58.	There are higher costs of compliance to quality management practices.					
59.	There is difficulty in getting competent suppliers					
60.	There is organization-wide focus towards continuous improvement.					
61.	There is clear monitoring and evaluation criteria for improvements made.					
62.	There is clear direction on how to use information gained to improve product design and customer service.					
63.	Any other (please specify)					

64. Based on your experience are the benefits of implementing quality management practices greater than their disadvantages?.

Yes [ ]

No [ ]

Please explain your answer in the space provided below. If inadequate, attach an extra paper.

Thank you for taking time to fill out this questionnaire

APPENDIX III: LIST OF PHARMACEUTICAL MANUFACTURING COMPANIES IN KENYA AS AT 31ST MARCH 2008

1. Aesthetics Limited
2. Alpha Medical Manufacturers Limited
3. Autosterite East Africa Limited
4. Bayer East Africa Limited
5. Beta Healthcare International Limited
6. Biodeal Laboratories Limited
7. Bulk Medicals Limited
8. Coopers Kenya Limited
9. Cosmos Limited
10. Curacid Limited
11. Dawa Pharmaceuticals Limited
12. Didy Pharmaceuticals Limited
13. Diversey Lever Limited
14. Elys Chemical Industries Limited
15. Gesto Pharmaceutical Limited
16. Glaxo Smithkline Kenya Limited
17. Infusion Kenya Limited
18. Ivee Aqua (EPZ) Limited
19. Kam Industries Limited
20. Kenya Sterile Supplies Limited
21. Lab and Allied Limited
22. Macs Pharmaceuticals Limited
23. Manhar Brothers (K) Limited
24. Medivet Product Limited
25. Norbrook Africa EPZ
26. Norbrook Kenya Limited
27. Novelty Manufacturers Limited
28. Pharmaceutical Manufacturing Company Limited
29. Pharmaceutical Products Limited
30. PZ Cussons East Africa Limited
31. Reckitt Benkiser East Africa Limited
32. Regal Pharmaceutical Limited
33. Sino Kenya Pharmaceutical Limited
34. Sphinx Pharmaceuticals Limited
35. Twiga Chemical Industries
36. Universal Corporation Limited