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Evaluation of Quality Management Practices in Nigeria Pharmaceutical Industry

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Abstract

The paper evaluates quality management practices in pharmaceutical industries in Nigeria amidst the competition among companies in the industry that gives room for threats and opportunities from the outside environment, creating the need for quality management practices in order to win the market. The papery also examines factors affecting quality management practices of the industry in Nigeria and its relevance to the society. This paper makes use of survey design and multi-stage sampling technique to collect data from 96 respondents with the aid of 22-item well structured questionnaire from selected pharmaceutical companies in Ogun State, Nigeria. Data from this survey was tested by chi- square (X^2) at 0.05 alpha level. The result indicates that quality management has significant effect on production output and participation amongst employees, managers and organization as a whole. The paper concludes that manufacturer should be in a position to control the sources of product quality variation, namely materials, machine, method and men and also to ensure the correct and the most appropriate manufacturing and packaging practices.

Keywords: *Production, Quality Management, Pharmaceutical, Packaging*

Background to the Study

In the early twentieth century, quality management meant inspecting products to be sure they are manufactured to specification. During the World War 2, quality management became more statistical in nature. Statistical sampling methods were used to evaluate quality and quality control charts were used to monitor the production process. Quality management can be viewed as a solution to a lot of problem in the pharmaceutical companies. Its effect could be seen in the performance of the industry and products

profitability and in turn its effect on the nation's economic development. Quality of pharmaceutical products is derived by the physical plant design, space, ventilation, cleanliness and sanitation during routine production (Gennaro, 2000). Linderman 2004 asserts that most quality improvement activities require the creation of new knowledge for the organization. This suggests that the acquisition of knowledge is very important in achieving quality management. Quality management is defined by the International Organization for Standard (ISO) as a management approach for an organization centered on quality based on participation of all its members and aiming at long-term success through customer satisfaction and benefits to all members of the organization and to society (ISO 8402:1994). It could also be define d as pursuit of excellence, value for money, appropriate for use and customer satisfaction.

However, the pharmaceutical industry is a complex, delicate and complicated sector, because of the nature of its customers. Therefore, it is necessary to ascertain the quality of its product. Pharmaceutical industry is amongst the stringently regulated manufacturing unit (Dubey, 2011). Also, the importance of the pharmaceutical industry to the health care system cannot be overemphasized. The pharmaceutical industry, as a vital segment of the health care system conducts research, manufacturing and marketing of pharmaceuticals and biological products and medical devices used for the diagnosis and treatment of diseases (Mazumder, 2011). Thus, the Nigerian pharmaceutical industries are well regulated for obvious reasons. For instance, the effect of mistakes in product design or production is severe, fatal and can consequently lead to death or at least a re-use of drugs for treating the same ailments. However, it is believed that less than 0.1% of the chemical entities tested in the laboratory get to the market and takes up to 20-25 years of research and billions of naira.

The Competitiveness in the world market that gives room to threats and opportunities from external environment to any manufacturing industry including the Nigerian pharmaceutical industry based on its product made it necessary to set condition that support the industry in creating, adopting and implementation of quality management practices in order to win the market. Generally, competitive advantage suggests that each organization have one or more of the following capabilities when compared to its competitor, such as lower prices, higher quality, higher dependability and shorter delivery time (Munizu, 2013). This means that pharmaceutical products are manufactured with the purpose of treating diseases or ailments irrespective of the feelings or expectation of the customer.

The basic questions that are to be addressed are:

1. How does the practice of quality management affect pharmaceutical products?
2. What is the effect of quality management practices on the performance of pharmaceutical industry in Nigeria?
3. What are the possible prospects of quality management and the factors affecting its practices?

Therefore, the general objective of the paper is to examine the impact of quality management in pharmaceutical industries. Specifically, the paper intends to:

1. determine how quality management practices affects pharmaceutical products.
2. determine the effect of quality management practices on performance of pharmaceutical industry.
3. examine factors affecting quality management practices and possible prospects.

Thus, the guiding hypotheses for the research are as follows:

H_0: Quality management practice does not have significant effect on performance of pharmaceutical industries.
H_1: Quality management practice has significant effect on performance of pharmaceutical industries.

Literature Review

A management philosophy is driven by customer needs and expectations and focuses on continual improvement in a work process. In Nigeria, quality management practices are a philosophy not a science as it can often be born and lived on. That is, it can be improved upon and be adapted to differences within an organisation. However, the opening of markets, increased buyer-cost sensitivity, global competition and technological advancement has increased the levels of uncertainty in the pharmaceutical industry, and one major change is the emergence of generic product which threatens the sale of branded products. Generic products are product produced after expiration of patent by manufacturers other than the patent owner which are produced at cheaper price. In the 1980's pharmaceutical market depends on products, such that companies had developed and brought medicine to the market which are safe, effective and had no regulatory complaint. According to Bashe (2000), the increase in consumer power will fundamentally force pharmaceutical companies to change the ways they operate such that there will be need for an effective pharmaceutical quality assurance system.

In Nigeria, quality management practices are what pharmaceutical companies build their quality approach around in other to ensure quality and safe products. Moreover, the National Food and Drug Administration and Control Agency (NAFDAC) has been set up to test drug and food product for its identity, safety, quality, purity and stability before it can be produced and used. Hence, quality management practices are important for pharmaceutical companies due to stringent regulatory requirement, competitive market, global competition and emergence of generic products. Thus, this paper evaluates quality management practices in Nigeria pharmaceutical industry.

The concept of quality has been in existence for years, and most used term in everyday business with its meaning changing and evolving over time. Quality was defined as the totality of features and characteristics of a product or service that bears on its ability to satisfy given needs (Mazumber, Bottacharya, Abhisela, 2011). Although, with the passage of time, the idea of quality being something that needs inspection and correction has change to strategic meaning. In recent times, organisation that are successful

understand that quality provides a competitive advantage by putting their customer first and defining quality as satisfying customer expectations. Quality has eight dimensions (performance, features, reliability, conformance, durability, serviceability, aesthethics and perceived quality) which is an important ingredient to organisation success (Mazumber., Bottacharya, Abhisela, 2011).

Management is the ability to organize, coordinate and control human and also allocate non-human resources to achieve organizational set objectives or goals. According to Osamuwonyi and Igbinosa, (2005), it is defined as a process by which certain coordinated activities are directed using organizational resources with the aim of achieving organizational goals in an efficient manner.

Early work on quality management can be traced to 1949 when the Japanese Union of Scientist and Engineers (JUSE) formed a committee of scholars, engineers and government officials devoted to improving Japanese productivity and enhancing post war quality of life. According to Walton (1986), Deming and Juran influenced Japanese union of scientists and engineers (JUSE) committee to develop a course on statistical quality control for Japanese engineers followed by extensive statistical training and wide spread dissemination of Deming philosophy among Japanese manufacturers. According to Ehigie and Akpan, (2001), many organizational techniques fail because they neglect the people aspect of change just as employees are at the centre of organizational change with organizational improvement occurring only through quality management introduction when organizational members behavior changes.

The most pervasive approach in managing quality has been called quality management. It is the real and meaningful effort by an organisation to change its whole approach to business to make quality a guiding factor and everything the organisation does. Quality management provides managerial innovations as quality circles, equity circles, cellular manufacturing and just-in time production to improve organizational performance (Kruger 2001). Quality management is rapidly growing system of practices and tools for managing companies to provide customer satisfaction in a gradual and consistent changing world. The major ingredients of quality management, according to Mazumber, *et.al*. (2011), are strategic commitment, employment involvement, materials, technology and method of production, all of which are embedded into the element of pharmaceutical quality system that are:

1. Managerial review of process performance and product quality
2. Process performance and product monitoring
3. Corrective action and preventive action
4. Change control management system

Several studies have been carried out on quality management practices with prior studies measuring quality management through organizational performance using both financial and market criteria, return on investment (ROI), market share, profit margin (stock 2000). Although, many authors (kaynak, 2003; Douglas and Judge 2001; Henderick

and Singhal, 1996,1997 and 2001; and Eastern and Jarell 1998) argued that quality management leads to firm performance, but to the best of our knowledge, there is no profound study on evaluation of quality management practices in manufacturing industry such as the pharmaceutical industry. This is the motivation for this research work.

Research Methodology

The method used in this research work is the survey research method. It examines population by selecting and studying samples chosen from the population. This study was carried out in Ogun State, South West Nigeria. In carrying out this research work, the data used were obtained from both primary and secondary sources. The primary data used for this study were obtained through questionnaire and inferential statistics. A multi-stage sampling technique was used in selecting the respondents. The first stage is the purposive selection of Ogun State out of the 36 States of the federation. The second stage involves random selection of 5 pharmaceutical companies within the state. The third stage involves the random selection of 96 respondents from the various pharmaceutical companies. The analysis of data was done through Chi-Square (X^2). Also, descriptive statistic was used to analyze the data collected.

Data Analysis and Interpretation of Results

Table 1 presents the respondents' view of their understanding of quality management in an organization, especially in a pharmaceutical Company.

Table1: Understanding of quality management practice

Valid	Frequency	Percent
I have understanding of quality management practice	88	91.7
I have no understanding of quality management practice	2	2.1
I am not sure of the meaning of quality management practice	6	6.3
Total	96	100.0

Source: Field Survey 2015

From Table 1above, it can be seen that 88 (91.7%) confirmed that they understand what QM is all about while 2 (2.1%) thought otherwise, and 6 (6.3%) were not sure of the meaning of quality management.

Table 2 shows the adoption of quality management as a tool improving performance in the manufacturing sector

Table 2: Pharmaceutical Industry Adoption of QM as a Tool

	Frequency	Percent
Adoption of QM as a Tool	90	93.8
No Adoption of QM as a Tool	6	6.3
Total	96	100.0

Source: Field Survey 2015

From Table 2 above, it can be seen that 90 (93.8%) confirmed the adoption of TQM cost overrun has been experienced in the dealings of the company as is seen as a major problems affecting the company while 6 (12%) thought otherwise.

Table 3 presents some major factors affecting quality management practices which are shortage of knowledge and skills, poor implementation philosophy, poor managerial skills, lack of adequate commitment, poor leadership skills, lack of reward and recognition, inadequate training, lack of continuity among others.

Table 3: Factors Affecting Quality Management Practices

Factors	Percentage (%)
Shortage of knowledge and skills	83%
Poor implementation philosophy	86%
Poor managerial skills	91%
Lack of adequate commitment	82%
Leadership skills	90%
Lack of reward and recognition	79%
Inadequate training	66%
Lack of continuity	67%

Source: Field Survey 2015

Table 3 above shows the percentage ratings of all the factors affecting effective adoption of quality management practices as viewed by the respondents. The result shows poor managerial skill as the major factors with a percentage rating of (91%) followed by lack of leadership skills (90%), poor implementation philosophy (86%), shortage of knowledge and skills (83%), lack of adequate commitment (82%), lack of reward and recognition (79%), lack of continuity (67%) and finally inadequate training (86%).

Test of hypothesis

Hypothesis raised to guide and ascertain the achievement of the aim and objective of this study were tested using chi-square to analyze the likert-scale structured questionnaire for this purpose.

Table 4: Quality management practice production output

	Observed N	Expected N	Residual
Strongly agree	66	16.0	17.0
Agree	22	16.0	-5.0
Moderately agree	8	16.0	-12.0
Disagree	0	16.0	-16.0
Strongly disagree	0	16.0	-16.0
Total	96		

Table 5: Test statistics

	Quality management practice production output
Chi-square	28.625
Df	2
Asymp.sig	.000

$X^2 = \frac{[(OF-EF)^2]}{EF} = 28.625$

The alpha level is 0.05

The results above shows that chi-square calculated value of 28.625 is greater than the table value of 15.51, thus the null hypothesis is rejected and alternate hypothesis accepted. The result implies that quality management practices have significant effect on production output, which is a measurement of pharmaceutical industries performance.

Conclusion and Policy Recommendations

Quality management practice encourages participation amongst employees, managers and organization as a whole. The responsibilities that rest with the pharmaceutical manufacturer for the assurance of quality of product are tremendous and it can only be achieved by well organized work culture and complete engagement of the employees at the work place. It should be realized that National and International Regulations must be implemented systematically and process control should be practiced rigorously. Good manufacturing practices (GMP) are implemented systematically and process control is practiced rigorously. Product quality must be built into and not merely tested in the product. The pharmaceutical manufacturer assumes the major responsibility for the quality of his products.

Therefore, the paper recommends that managers at pharmaceutical industries should focus on adoption of quality management practices to enhance their performance. Control decisions must be based solely on considerations of product quality and organizational performance. Operations of pharmaceutical industry must adhere rigidly to the established standards or specifications as determined by systemic inspection, sampling and testing, and should constantly strive for improving the levels of the current standards or specifications. Finally, new case studies should be carried out to prove the feasibility of quality management practices.

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