Effect of Total Quality Management on Performance of Indian Pharmaceutical Industries

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Abstract

The pharmaceutical industries are heavily regulated and the reasons are obvious: mistakes in product design or production can have severe, even fatal, consequences for patients which sometimes leads to recall of the drug from the market; where the fact is that out of 10,000 NCEs (New Chemical Entities) tested in the lab, only one reaches to the market and that too takes almost 18-20 years of research and approximately $800 million. Hence quality and its management are very critical in this industry. Total Quality Management (TQM) acts as an umbrella under which everyone in the organization can strive for customer satisfaction, reduce cost and wastage and increase the efficiency of services. This paper surveys and reviews various Quality Management practices including ISO implementation in Indian pharmaceutical industries to explore the relationship between Total Quality Management practices and performance of the company. It also attempts to identify and analyze the significant factors affecting Total Quality Management implementation in Indian Pharmaceutical Industries. The survey is carried out by a self designed questionnaire and circulated to select pharmaceutical industries in India.

Keywords

Total quality Management, Company performance, Factors affecting TQM.

1. Introduction:

Total quality management (TQM) has been defined as an integrated organizational effort designed to improve quality at every level. TQM is also defined as quest of excellence, fitness for use, value for money, customer satisfaction etc. The International Organization for Standards (ISO) defines TQM as, "TQM is a management approach for an organization, centered on quality, based on the 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

The concept of quality has existed for many years, though it’s meaning has changed and evolved over time. In the early twentieth century, quality management meant INSPECTING products to ensure that they met specifications. In the 1940s, during World War II, quality became more STATISTICAL in nature. Statistical sampling techniques were used to evaluate quality and QUALITY CONTROL charts were used to monitor the production process. In the 1960s, with the help of so-called “quality gurus,” the concept took on a broader meaning. Quality began to be viewed as something that encompassed the entire organization, not only the production process. Since all functions were responsible for product quality and all shared the costs of poor quality, quality was seen as a concept that affected the entire organization.
Since the mid 80’s Total Quality Management (TQM) is considered as the universal remedy for a range of organization problems including organization performance. Today, successful companies understand that quality provides a competitive advantage. They put the customer first and defined quality as meeting or exceeding customer expectations. TQM evolution has been summarized in the following table:

### Quality Movement from Inspection to TQM

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Inspection</th>
<th>Statistical Quality Control (SQC)</th>
<th>Quality Assurance (QA)</th>
<th>Total Quality Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td>Measurement of specifications</td>
<td>Control of processes</td>
<td>Distribution of quality responsibility to functional areas</td>
<td>Continuous quality improvement at every level, at every place and at every stage</td>
</tr>
<tr>
<td><strong>Focus</strong></td>
<td>Uniform product quality</td>
<td>Reduction in inspection work</td>
<td>Evaluation at all stages</td>
<td>Customer (internal and external) satisfaction</td>
</tr>
<tr>
<td><strong>Tools</strong></td>
<td>Gauges and measurement techniques</td>
<td>Statistical quality control tools and techniques</td>
<td>Quality planning, documentation and quality systems</td>
<td>Commitment, participation, motivation, education &amp; training, organization development</td>
</tr>
<tr>
<td><strong>Responsibility for quality</strong></td>
<td>Inspection department</td>
<td>Production department</td>
<td>All departments</td>
<td>Top management leadership with everyone in organization</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td>Inspection, sorting grading</td>
<td>Trouble shooting and controlling the quality</td>
<td>Assuring to build quality planning programme design and programme control</td>
<td>Strategic management, team involvement and action research</td>
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### 1.1 Definitions:

To fully understand the TQM movement, we need to look at the philosophies of notable individuals called ‘Quality Gurus’ who have shaped the evolution of TQM. **W. Edwards Deming** stressed on improving quality through the use of statistical quality control technique. Deming proposed 14 principles of quality management. Some of which are- Top Management commitment to quality, Continuous search for and correction of quality problems, Effective communication between supervisors and employees, Company wide training and education in quality. **Joseph Juran** defined Quality as *Fitness for Use*. Juran is also credited for developing the concept ‘Cost of Quality’. He has originated the idea of Quality Trilogy i.e. Quality planning, Quality control and Quality Improvement. **Armand V. Feigenbaum** proposed the concept of ‘Total Quality Control’ and advocated the idea of a work environment where quality developments are integrated throughout the entire organization, where management and employees have a total commitment to improve quality and people learn from each other’s successes. This philosophy was adapted by the Japanese and termed “company-wide quality control.” **Philip B. Crosby** developed the phrase “Do it right the first time” and the notion of *zero defects*, arguing that no amount of defects should be considered acceptable. **Kaoru Ishikawa** is best known for the development of quality tools called cause-and-effect diagrams, also called fishbone or Ishikawa diagrams.

Another concept of TQM is continuous improvement or **KAIZEN**. Traditionally change meant for major organizational restructuring. But Japanese introduced the idea of gradual improvement. The idea behind this was, ‘Small changes can be done quickly, easily and continuously without any significant investment. Small-
small changes make big improvements for the organizations, employees and customers’. Japanese called it ‘Kaizen’ - A regular habit of thinking new ideas. 
There are two approaches adopted by the companies for continuous improvement:
 a. The PDCA cycle: Plan-Do-Check-Act and
 b. Benchmarking: The ability to learn and study how others do things is an important part of continuous improvement.

**ISO 9000 standards:**
The International Organization for standardization (ISO) is an international organization whose purpose is to establish agreement on international quality standards. It has been created to develop and promote quality. ISO 9000 consists of a set of standards and a certification process for companies. By receiving ISO 9000 certification, companies demonstrate that they have met the standards specified by the ISO. The standards are applicable for all types of companies and have gained global acceptance. In many industries ISO certification has become a requirement for doing business.

1.2 **Effect of substandard Quality:**
The Bhopal gas tragedy occurred on December 3rd 1984, when tons of methyl isocyanate, hydrogen cyanide and other lethal gases began spewing from Union Carbide’s pesticide factory in Bhopal. Nobody outside the factory was warned because the safety siren was turned off. By the time the people of Bhopal could realize anything it was too late. Thousands of people lost their lives in this tragedy. The Bhopal disaster was a total failure as described by Lulla S. showing failure of product, process, system and management.

1.3 **Quality Management and Pharmaceutical Industry:**
Apart from safety, the pharmaceutical industry is heavily regulated and the reasons are obvious: mistakes in product design or production can have severe, even fatal, consequences for patients (Gough, 1999). Examples of recall of the drugs from the market are:

a) **VIOXX**- Vioxx is in a class of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). Vioxx was used to reduce pain, inflammation and stiffness caused by osteoarthritis, rheumatoid arthritis and certain forms of juvenile rheumatoid arthritis; to manage acute pain in adults; to treat migraines; etc. It got approval from US FDA in 1999. Merck, the manufacturer of Vioxx, voluntarily withdrew it from the market due to safety reasons- increased risk of Heart attacks. Within this period nearly 28000 or more cases of heart attack or sudden cardiac deaths were caused by Vioxx.

b) **Thalidomide (Kevadon)** was launched in 1957 as a treatment for morning sickness during pregnancy. Heavily marketed, its sales soon spread abroad. It took four years before the connection was made between the drug and its side-effects. By which time at least 10,000 children had been born with shortened limbs and other complications. The scandal transformed drug regulation. Drug Research regulations made more stringent.

To ensure quality and safe products, pharmaceutical companies build their quality approach around Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and their In-house Standard Operating Procedures (SOPs).

Thus quality is important for pharmaceutical companies due to: Stringent Regulatory requirements; Competitive market; Global competition; Technological advances and Emergence of generic product.
2. Literature Survey:

A number of studies have been conducted (for national and international comparisons) to explore the relationship between Quality Management Practices and their impact on the performance of the organization. Performance here means: Financial performance, Quality of products, Customer satisfaction, Employee satisfaction, Market performance, Business results, Cost and waste reduction, Safety etc.

An international quality study (IQS) conducted by Ernst & Young for the American Quality Foundation suggested that quality is a crucial factor in major manufacturing organizations in the USA, Canada, Japan and Germany (Sohal and Eddy, 1994). The International Quality Study has made a significant contribution to understanding the link between quality management practices and business benefits among organizations in the USA, Canada, Japan and Germany. Kim et al. (1997) studied the quality strategies and improvement programs amongst leading manufacturing companies in western economies and found that the most successful firms followed a step-by-step quality staircase to achieve competitive edge. The steps to climb on are conformance, reliability, performance and customization and a sequential follow up of these steps leads to achieving competitive edge. Lassaad Lakhal et al. (2004-2005) conducted a study to find out the relationship between quality management practices and their impact on performance. They collected data from 133 Tunisian companies. The results revealed a positive relationship between Quality Management Practices (QMP) and organizational performance. Calvin London (2005) studied Management effects on Quality policy implementation in pharmaceutical companies and the nature and extent of structured programs for policy implementation. The study revealed that the levels of commitment and involvement shown by management (both senior and middle management) had significant effects on the success of the quality policies. Where the perceived levels of support were lowest, policies took a long time to be implemented, consumed resource and resulted in approved policies that did little to meet their overall objectives for the company. The role of senior management is one of the most significant factors in creating successful cultural change and policies need to originate from a senior management level.

The picture is, however, different and unclear for developing economies. Quality literature abounds with successful examples and cases of western economies adopting quality initiatives, but very little has been reported on quality issues in developing economies. Only recently, reports are appearing on quality studies relating to work culture, impacts of government policies, technological diversification, etc. specific to developing countries.

In the case of India, only a few attempts have been made in the past to understand how Indian pharmaceutical companies are competing in domestic and international markets. Motwani et al. (1994) conducted a study to identify the degree to which quality management practices were present in Indian manufacturing organizations. The study showed that the modern concepts of quality management were practiced by the large Indian manufacturing organizations. Quality certification is becoming an acceptable way of enforcing quality concepts in India. According to a 1995 survey (Confederation of Indian Industries, 1995) among ISO 9000 certified companies, 54 per cent of 330 respondents stated that there had been an improvement in their product and process quality after obtaining certification.

An empirical study conducted by Gupta A. on Quality Management Practices of ISO vs non-ISO organizations in India suggest that ISO and non-ISO organizations do differ in their quality management practices. ISO 9000 registered manufacturing organizations in this study had formal commitment to quality management.

A review of the literature has indicated that plenty of studies have been conducted on Total Quality Management practices in western economies but very few attempts have been made for a comprehensive analysis of quality initiatives in Indian Pharmaceutical Industries. With this in mind, there is a need for further research to identify the Quality management practices adopted by the Indian Pharmaceutical Companies, impact of TQM on performance of the company and to predict the future directions of quality initiatives for Pharmaceutical Companies.
3. Relationship of Total Quality Management With Company’s performance in Indian Pharmaceutical Industries

The Indian pharmaceutical industry mainly comprises of Indian subsidiaries of Multi National Companies (Glaxo Smithkline, Merck, Pfizer etc.), Indian owned companies (Ranbaxy, Dr. Reddy’s, Cipla, Glenmark, Cadila) and numerous small scale industries scattered in all parts of India. These companies can also be classified on the basis of annual turnover, number of patents, number of employees and number of formulations.

In this paper, an attempt has been made to survey and review the Quality Management Practices including ISO implementation, and further analyze the significant factors affecting the implementation of TQM in Indian pharmaceutical industries. The questionnaire used in the works of Kakkar and Narang (2007) has been modified and customized to the specific requirements of the Indian Pharmaceutical Industry. Initially this questionnaire was circulated to select respondents in the Indian pharmaceutical industry as part of the pilot study. Based on the responses received in the pilot study, the main factors affecting the implementation of Total Quality Management are: Top Management Commitment, Leadership, Quality Management, People Management and Training, Customer Focus and Supplier Quality. The importance of these factors in the context of the Indian Pharmaceutical Industry is tabulated below:

<table>
<thead>
<tr>
<th>Factor affecting TQM</th>
<th>Importance of the Factor in the context of Indian Pharmaceutical Industry</th>
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<tbody>
<tr>
<td>Top Management Commitment</td>
<td>Top management commitment was found to be the most significant factor affecting the implementation of Total Quality Management. Top management of the respondent companies assumed responsibility for quality. It was found that the level of commitment and involvement shown by the senior management had noticeable effects on the success of the company.</td>
</tr>
<tr>
<td>Leadership</td>
<td>Leadership is an important factor for Total Quality Management. An effective and dynamic leader can lead a successful team and subsequently make a profitable organization</td>
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<tr>
<td>Quality Management</td>
<td>Quality management includes availability of quality information as well as usage of quality information. Timely and accurate information about the manufacturing process is important to control the process and reduce defective products. Immediate problem solving keeps the process in control. Similarly quality information usage is also an important feature of quality information management. Although quality information is available; only proper and effective use of it leads to quality improvement.</td>
</tr>
<tr>
<td>People Management and training</td>
<td>Employee training is an important factor of quality management. Training is an efficient way to increase employees’ ability to perform better. An organization which fully utilizes the skills of its workers’ ability is on its way to achieve organizational objectives.</td>
</tr>
<tr>
<td>Customer Focus</td>
<td>The main objective for a product or service design is to meet or exceed the customers’ expectation and thus to satisfy the customer while making a reasonable profit. Customers are the driving force for product and service design. A customer oriented or customer focused organization maintains its competitive advantage.</td>
</tr>
<tr>
<td>Supplier &amp; Vendor Quality</td>
<td>Supplier and vendor quality is also an important dimension of quality management as defective materials, parts and services lead to product and process quality problems. Maintaining good supplier and vendor relationship is acknowledged as a key factor in maintaining competitive advantage.</td>
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The responses from the pilot study were encouraging. The questionnaire is being modified to encompass the specific requirements of all companies in the Industry. Statistical analysis would be done using SPSS. Finally a linkage between Total Quality Management Practices and Indian Pharmaceutical Industries’ Performance will be established.
7. References:


