Role of Quality Management in Pharmaceutical Development: Evidence from Islamabad and Lahore

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ABSTRACT

The aim of this paper is to investigate the employee's perceptions of the impact, of Total Quality Management (TQM), on their roles within the organization and how they perceived the effectiveness of the quality processes in Pakistan Pharmaceutical industry. The universe of this study was the employees of Pharmaceutical industry in Islamabad and Lahore. For this purpose survey method was used by using questionnaire as a tool for data collection. The results have shown that Employee Training and Development, Employee Performance, Quality Process and Team Work are significant factors with the Total Quality Management and correlated with each others. The result shows the application of TQM principles addresses some of the key challenges facing the organization. The study was faced by certain limitations and included time constraints and resources constraints which limited this research to only Islamabad and Lahore offices, of the Pharmaceutical companies. The present study found support that pharmaceutical companies faced the same difficulties with TQM implementations as experienced in other industries. These include achieving a culture of continuous improvement, overcoming a lack of trust and understanding the TQM process itself, and what they were, as a company, trying to achieve. These problems are not new and many companies have difficulties in implementing TQM. Pharmaceutical companies also followed the path of achieving a quality certification; namely, ISO 9000 accreditation, in the pursuit of excellence.

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1. NTRODUCTION

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Industry reform is challenging the fundamental focus of the pharmaceutical industry and its customers. Demands for quality have never been higher. Pharmaceutical companies must meet many new challenges to ensure efficient business operations. There are external challenges from competitors, generic drug manufacturers, health-care organization, in additional to internal challenges to decrease the cost of sales, Research and Development (R&D), and manufacturing. Government's guide lines in the form of regulatory requirements need to be received, interpreted and disseminated in timely manner to ensure compliance. Quality is now major differentiator in today's increasingly competitive business environment. The TQM philosophy stresses a systematic integrated, consistent organization –wide perspective involving everyone and everything. Quality standards for pharmaceuticals have been built up for the years from experts from industry, pharmaceutical authorities, regulatory agencies and academia and based on experience and the need to look after the safety and efficacy of the product for the sake of patient's health. TQM is a philosophy that embraces concepts, methods, tools and techniques to form a language which is understood and applied as a business strategy at the "top-floor" and as a functional strategy at the "shop-floor". This approach assists organizations to integrate business activities in leadership, people and customers' focus, planning, quality assurance of processes, and information and analysis. These activities, when effectively linked together, would lead to sustainable world class performance to customers' satisfaction, employee relations, operating performance and business performance. TQM or Continuous Quality Improvement (CQI) is a management philosophy currently used in many industries to improve the "quality" of products and services. Incited by impressive results in other industries, this compelling and logical approach has begun to penetrate into the thinking of health-care organizations. TQM is an organized, integrated system of CQI aimed at meeting customers' expectations.

1.1 Challenges in the Pharmaceutical Industry

The pharmaceutical industry has an increasingly complex and dynamic environment. There have been a lot of change, in the recent years, in the pharmaceutical industry and this trend is likely to continue. The openings of markets, increased buyer-cost sensitivity, global competition and technological advancements have increased levels of uncertainty. There has been an inexorable rise in patient expectations, increased costs of health-care and the inability of economics to meet the increased costs. Consequently governments have introduced a number of measures aimed at increasing competition and accountability and thus reducing costs. One major change has been the emergence of generic drugs, which is threatening the loyalty to major branded drugs. A generic product is product manufactured after patent expiry by another manufacturer, normally at a cheaper price. The growth of many organizations has rested on the success of technological advances in manufacturing new product.

1.2 Smaller Companies Make Inroads

As barriers come down, and customers' demand change then smaller companies begin to make inroad penetration into the marketplace. The smaller companies are competing on flexibility and innovation, adapting to changing market conditions.

1.3 Changing Consumer Demand

In the 1980s, the pharmaceutical marketplace was primarily product driven. Companies have developed and brought medicines to market that were safe, effective and without regulatory compliant. The consumer is now more aware, educated and demanding. Bashe (2000) states that the increase in consumers' power will fundamentally force pharmaceutical companies to change the way they do business.

1.4 Requirement for New Approaches

Technological advances means increasingly clinical development will be done electronically and remotely. Consequently future clinical development and professionals will need to have technical therapeutic skills, IT competency highly developed communication skills and commercial abilities. The pharmaceutical industry will need to move beyond its conservative outlook and embrace an entrepreneurial approach attracts new skills and fresh ideas.

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1.5 Quality Management in the Pharmaceutical Industry

Along side other industries where safety is critical, the pharmaceutical industry is heavily regulated and for obvious reasons: mistakes in product design or production can have severe and even fatal, consequences for patients. The manufacturer shall establish and implement effective pharmaceutical Quality Assurance (QA) system, involving the active participation of the management and personnel of the service involved. To ensure quality and safety of the products, pharmaceutical companies build their quality approach around good manufacturing practices (GMP).

2. LITERATURE REVIEW

TQM has been defined as a new way of organizing a strategy (Hayes and Wheelwright 1984), achieving excellence (Juran 1951), and meeting and exceeding customer expectations (Buzzell and Gale 1987). A consensus (Dean and Bowen 1994) is however emerging that organizations embracing TQM are founded on three principles. The first is, customer focus, defined as meeting and acceding customer needs. The second is continuous improvement, defined as attempting to create gains in performance from incremental innovations in organizational processes. The third principle is teamwork, defined as collaborating with all organizational members, customers, and suppliers. These principles focus the organization on satisfying current and anticipated customers' needs by creating value through cost and customer-driven features in their markets (Jacob 1993). Implementation of these three principles typically requires "radical change" (Munroe-Faure and Munroe- Faure 1992: 8) or a "paradigm shift" (Blackburn and Rosen 1993) in organizational design.

A fourth type of work has been identified by Tushman (1979), in his studies relating subunit work characteristics to subunits' structure and performance. Such work has non programmed means but programmed ends. This work has clear well-defined and programmed output/goal, but entails changing the means by which work is carried out. Work or task shows "continuous improvement" when done with uninterrupted improvement by line workers, define problems, decipher cause and

effect relationships, and propose testing specific approaches for doing the work. These efforts for improvement cannot be completely standardized, because problem solving cannot be routine, by definition, as it relies on creative thinking and active information searching. Work under TQM in this sense is "dual". TQM combines two distinct types of tasks-standardized production and continuous improvement, execution and conceptualization-into one job role.

TQM relies on the tools of scientific management and experimentation to define the "best practices" used in production; but not every step of the improvement efforts can be standardized. This is because continuous improvement is problem-solving in nature, requiring information search and analysis to identify underlying relationships, determine feasible solutions, and evaluate alternatives (Lillrank and Kano 1989). However, it would be misleading to characterize this work as innovation (non programmed ends and means), because its objectives are the achievement of well-defined goals such as "increasing quality by 3%" or "reducing defects by 5%," or a broad, but directionally oriented set of goals such as "reduced costs" or "increased quality." We have therefore labeled it continuous improvement.

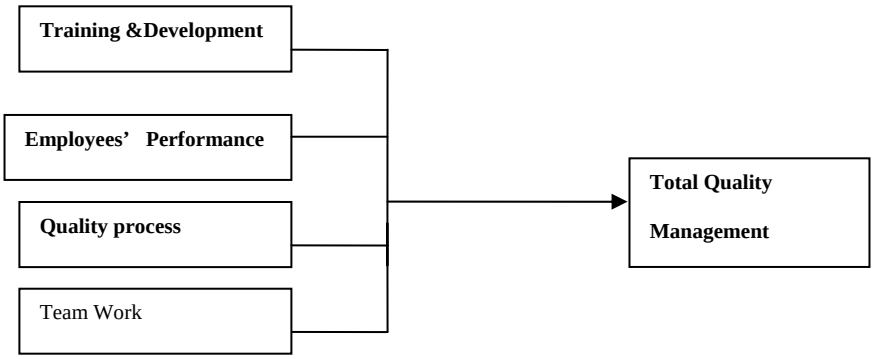
TQM is ultimately a challenge for each individual employee to accept or reject. Most TQM implementations take place in existing and on-going organizations (Wilkinson, McCabe and Knights 1996) where the worker's role is often limited to the standardized. In such cases, the change to TQM appends continuous improvement tasks to standardized production. The change in role is neither insignificant nor non problematic. The significance of this change for employees is reflected in the imperative given in both the practical and managerial literatures on the "social" aspects of TQM implementations including training, culture, and motivation (Tuckman 1994). When combined in the TQM job, employees may perceive standardized production and continuous improvement work as posing illegitimate, irreconcilable, or conflicting demand.

Human Resource Management (HRM) is known to be a subset of a wide-ranging management process that is oriented towards and incorporated in the company strategy (Graf 2007). Consistent with this perspective, the area of HRM is known, including the processes and practices such as recruiting, selecting, motivating, training, compensating and retaining workers (Stone 2007). This suggests that an organization with successful HRM practices could help to improve the well-being of employees. According to Churchill, Ford and Walker (1976), since the salesmen's well-being and performance are affected by company policies and management actions, the management may modify company policies and procedures specifically on salesman compensation, promotion and sales training in order to improve the morale level among the sales force. Salesmen are more effective in their jobs when management furnishes them with satisfactory technical backup, information and training to assist them in handling unusual demands arising from the job (Churchill, Ford and Walker 1976). A critical component of TQM initiatives is that of employees' involvement which requires employees to take responsibility for the quality of their work and demands their active participation in the search for continuous improvement (Wilkinson, McCabe and Knights 1996). Successful implementation of TQM depends heavily on changes in employees' attitudes and activities (Guimaraes1996). Thus for the employer introducing TQM to gain employee commitment and co-operation rather than just compliance is the most important aspect and for this to occur a change of culture is required to include the greater involvement of employees in the decision-making process (Hill 1991). A central need emphasized (Snape 1996) is the development of a "quality culture" allowing all employees from top management to floor level in order to develop a commitment to continuous improvement as an integral part of their daily work. However, it has been suggested (Snape 1996) that the proponents of TQM have understated the difficulties of

winning employee commitment and focus on an overtly limited range of change levers.

On the basis of literature review it is conceptualized that following factors are important for the discussion of theoretical framework.

CONCEPTUAL FRAMEWORK



Source: McAdam, Rodney and Barron, Nigel (2002).

2.1 Conceptual Framework

2.1.1 Training

Training is claimed to be one of the essential features for improving quality (Brown 1994) and to deliver service quality competently and confidently (Berry and Parasuraman 1992). Since poor training is one of the reasons for a lack of quality in human service then training will be able to minimize the risk of service failure.

2.1.2Teamwork

Teamwork is often seen in the academic literature as a means of supporting willingness to deliver service quality (Berry and Parasuraman 1992). Through support from team members, motivation for providing quality service is likely to continue and effective teamwork tends to develop capabilities for delivering a high level of service quality (Tjosvold, Moy and Sasaki 1999). Other studies have found that weak service performance is strongly associated with a lack of teamwork; hence, service failure can be minimized by team working (Redman and Mathews 1998). When effective, a team tends to develop employee commitment towards customer service, and the capability of delivering a high level of service quality.

2.3 Purpose of the Study and Hypothesis Development

i. To understand the employees' perception of the impact of Total Quality Management on their roles within the organization and
ii. How employees perceived the effectiveness of the quality processes in Pakistan Pharmaceutical industry.

Hypothesis

The study examines the following hypothesis:

H10. There is no any positive and significant relationship between employee's perceptions and Total Quality Management
H1a. There is a positive and significant relationship between employee's perceptions and Total Quality Management.

H20. There is a no any positive and significant relationship between perceived effectiveness and quality processes
H2a. There is a positive and significant relationship between perceived effectiveness and quality processes.

3. METHODOLOGY

The data for this study were collected in 2009 from 5 different companies of Islamabad, Rawalpindi & Lahore. The result of an employee opinion survey, which was issued to over 175 employees, is summarized. A total of 158 surveys (90) percent were returned.

3.1 Correlation and Regression Analysis

Table-1: Descriptive Statistic

	Mean	Std. Deviation	N
Total Quality Management	6.5250	.79074	158
Training & Development	5.8933	.69971	158
Employee Performance	5.7766	.64412	158
Quality process	5.1000	.54772	158
Team Work	5.8289	.68981	158

Table-2: Correlation

		Total Quality Management	**Training & Development**	**Employee Performance**	**Quality process**	**Team Work**
Total Quality Management	Pearson Correlation	1	.699**	.651**	.399**	.321*
	Sig.(2-tailed)		.000	.001	.000	.005
	N	158	158	158	158	158
Training & Development	Pearson Correlation	.699**	1	.721**	.455**	.321*
	Sig.(2-tailed)	.000		.000	.000	.002
	N	158	158	158	158	158
Employee Performance	Pearson Correlation	.651**	.721**	1	.431**	.411**
	Sig.(2-tailed)	.001	.000		.000	.000
	N	158	158	158	158	158
Quality process	Pearson Correlation	.399**	.455**	.431**	1	.422**
	Sig.(2-tailed)	.000	.000	.000		.000
	N	158	158	158	158	158
Team Work	Pearson Correlation	.321**	.321*	.411**	.422**	1
	Sig.(2-tailed)	.005	.002	.000	.000	
	N	158	158	158	158	158

* Correlation is significant at the 0.05 level (2-tailed).

Table-3: Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.787(a)	.619	.427	.2297

Table-4: ANOVA (b)

MModel		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	18.882	5	6.294	25.174	.000(a)
	Residual	13.440	153	.270		
	Total	34.292	158			

Table-5: Coefficients (A)

MModel		Un-standardized Coefficients		Standardized Coefficients	T	Sig.
		B	Std. Error	Beta		
1	(Constant)	5.542	.214		13.900	.000
	Training & Development	.499	.102	.959	4.981	.000
	Employee Performance	.339	.115	.433	2.741	.001
	Quality process	.281	.138	.318	2.510	.002
	Team Work	.437	.098	.234	2.497	.002

4. RESULTS AND DISCUSSION

The result of an employees' opinion survey from, which was issued to over 175 employees, is summarized. A total of 158 surveys (90) percent were returned.

4.1 Training and development

Responses to this category showed a considerable amount of variation with induction and awareness training for new employees receiving the most positive responses, while multi-skilling for existing employees gave the High survey result of employees that tended to agree with the statement that there is adequate opportunity for learning about available job openings.

4.2 Employees' Performance

The High percentage result recorded acknowledged that employees believe that the company does make adequate use of recognition and rewards, other than money, to encourage good performance.

4.3 Quality process

The results from this category were the most positive within the entire employee opinion survey with employees consistently giving favorable results to all questions. The question which gave the most positive response was the employees' acknowledgement that the quality improvement process is considered as an important priority.

4.5 Teamwork

Overall, the favorable response to this category was evaluated. The employees felt most favorable answer to all questions, was "good co-operation between work groups in their department".

6. CONCLUSIONS AND RECOMMENDATIONS

The research undertaken reveals that a significant percentage (over half) have adopted and implemented TQM. It was also clear that those organizations that have implemented TQM did so in response to the difficulties they were facing due to changes in the industry. Increasing customer demands, globalization, the emergence of generic drugs, pressure to reduce costs, particularly in R &D, inroads into the marketplace made by similar companies, are some of key challenges in the pharmaceutical industry. Those pharmaceutical companies faced the same difficulties with TQM implementations as experienced in other industries. These include achieving a culture of continuous improvement, overcoming a lack of trust and understanding the TQM process itself and what they were, as a company, trying to achieve. These problems are not new and many companies have difficulties in implementing TQM. Pharmaceutical companies also followed the path of achieving a quality certification; namely, ISO 9000 accreditation, in the pursuit of excellence. Certification is attractive as a means of impressing new customers and convincing existing ones that they are dealing with a progressive company, which is continually seeking improvements. However certification was seen as a stepping-stone on the journey towards excellence. Certification was found to represent a milestone, a recognition that progress is being made and TQM efforts are paying off. The survey indicates that commitment to TQM among senior management is high.

Strong leadership has directed companies to attempt to make the TQM process "belong to the company" and so foster employees' ownership. Overall, the case results revealed that the organization had made progress in a number of key TQM aspects such as improving process, implementation its quality systems, procedures and using IT to improve the information flow, particularly to external customers.

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