International Journal of Pharmaceutical Science and Research
ISSN: 2455-4685
Impact Factor: RJIF 5.28
www.pharmacyjournal.net
Volume 2; Issue 6; November 2017; Page No. 01-07

Total quality management practices in pharmaceutical industry: A study of selected companies in Andhra Pradesh and Telangana states

[1] K Vijay Kumar, [2] Dr. R Sivaram Prasad
[1] Assistant Professor, Dept. of Regulatory affairs, Chalapathi Institute of Pharmaceutical Sciences, Guntur Andhra Pradesh, India
[2] Research Director, Acharya Nagaruna University, Guntur, Andhra Pradesh, India

Abstract
Total Quality Management (TQM) is a management approach for an organization centred 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. This research work therefore aimed at assessing the TQM practices and its effect on organizational performance in Selected pharmaceutical industries in AP and Telangana states. The company needs to find ways to surviving in the increasing competitive market and TQM as a strategic Management tool can be used for improving the competitiveness, effectiveness and flexibility of the whole organization. A population of 1200 workers from ifferent pharmaceutical industries comprising both senior and junior staff was used for the study. Primary data for this research was collected using a well designed and structured questionnaire which was made up of both close ended and open ended questions. The key findings showed that selected pharmaceutical industries is practicing TQM but it is yet to implement it to the highest level of subscribing to a quality award system. The implementation of TQM is at the quality assurance level. It was found out that management inactions undermined leadership commitment to quality and rendered TQM practices ineffective. It was concluded that there was the need to procure modern equipment to boost production. Again the firm needs to diversify key portfolio in order to spread the overhead cost. Management must work to build trust amongst staff to improve on team work. It is also recommended that the company subscribe to a quality award system. For instance ISO certification can help selected pharmaceutical industries practice TQM to the highest level to ensure customer confidence in the company's products.

Keywords: TQM, pharmaceutical company, GMP, ISO

1. Introduction
Any organization in any line of business requires a quality management program or some sort of quality program that is instituted from executive management down to the lowest level employee. While each particular function within an organization requires quality processes modelled after its own unique requirements, this individual quality processes should be designed and established based on the principles of the overall quality management program. One of such quality programmes is Total Quality Management (TQM). Total Quality Management (TQM) has been defined as an integrated organizational effort designed to improve quality at every level (Dale, 1999). TQM is also defined as a quest for excellence, fitness for use, value for money, customer satisfaction etc (Mohanty and Lakhe, 1994). The International Organization for Standards (ISO) defines TQM as, ―a management approach for an organization, centred 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 (ISO8402:1994).TQM as noted by Oakland (1993) as a strategic management tool that can be used for improving the competitiveness, effectiveness and flexibility of the whole organization. The concept of quality has existed for many years, though its 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 (Dhalla, 2010).

Total Quality Management (TQM) is a management approach for an organization centred 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. This research work therefore aimed at assessing the TQM practices and its effect on organizational performance in different pharmaceutical companies. The company needs to find ways to surviving in the increasing competitive market and TQM as a strategic Management tool can be used for improving the competitiveness, effectiveness and flexibility of the whole organization. A population of 1200 workers from different pharmaceutical companies comprising both senior and junior staff was used for the study. Primary data for this research was

collected using a well designed and structured questionnaire which was made up of both close ended and open ended questions. The key findings showed that the companies are practicing TQM but it is yet to implement it to the highest level of subscribing to a quality award system. The implementation of TQM is at the quality assurance level. It was found out that management inactions undermined leadership commitment to quality and rendered TQM practices ineffective. It was concluded that there was the need to procure modern equipment to boost production. Again the firm needs to diversify key portfolio in order to spread the overhead cost. Management must work to build trust amongst staff to improve on team work. It is also recommended that the company subscribe to a quality award system. For instance ISO certification can help to practice TQM to the highest level to ensure customer confidence in the company's products.

2. Significance of the Study

This study will enable the management of selected pharmaceutical industries and other similar pharmaceutical companies in India to identify key TQM practices which could be employed to bring improvement in organizational performance. The study will also help management of the company to identify ineffective TQM practices that exist in the company and how to remedy these ineffective practices. The study will offer management the opportunity to know whether ineffective TQM practices affect quality performance at selected pharmaceutical industries. This will enable management to come out with strategies which will help improve quality performance and eventually lead to meeting standards at both the domestic and foreign fronts thereby leading to customer satisfaction. The study will throw more light on TQM practices as a determining factor for quality performance and organizational performance as a whole. The research will again give impetus to the quest for growth and development by enabling management to chart a course for growth and development by eliminating the bottlenecks in their endeavours.

3. Methodology

Methodology includes research design and strategy, population of the study, research instruments, data collection procedure, data analysis and study area.

3.1 Research Design and Strategy

Methodology can be referred to as the theoretical analysis of the method appropriate to the field of study or the body of the methods and principles to the branch of knowledge (Kotler Armstrong, 2006). Research methodology is a way to systematically solve the research problem. It may be understood as a science of studying how research is done scientifically. It is necessary for the researcher to know not only the research methods/techniques but also the methodology. Researchers not only need to know how to develop certain indices or tests, how to calculate the mean, the mode, the median or the standard deviation or chi-square, how to apply particular research techniques, but they also need to know which of these methods or techniques, are relevant and which are not, and what would they mean and indicate and why. Researchers also need to understand the assumptions underlying various techniques and they need to know the criteria by which they can decide that certain techniques and procedures will be applicable to certain problems and others will not. All this means that it is necessary for the researcher to design his methodology for his problem as the same may differ from problem to problem. For this research, quantitative approach was employed.

3.2 Population of the Study

The study population is the aggregation of element from which the sample is actually selected. It is the aggregation or the totality of all members or units from which information could be obtained (Rubin and Babbie, 2001).

For the fulfillment of the goal, the research has been performed by selecting 25 companies on convenience basis of AP and Telangana states. These companies has classified as small, medium and large companies on the basis of annual gross product (Installed capacity). The research also taken the perception that the production and process skill set is based on technocrats from each company.

Among all the selected industries, sixty (60) members of management team, One hundred and sixty (160) senior staff and Nine hundred and Eighty (980) junior workers constituted the population of the study; this made the total population of the study is one thousand and two hundreds (1200). Due to the fact that the population of the study was relatively small, the study used census or total enumeration to collect data from the whole population. Complete enumeration consists of using each and every unit of the population in the study. The study did not use any sampling technique.

3.3 Research Instrument

Primary data for this research was collected using a well designed and structured questionnaire for data collection. A questionnaire is a pro-forma containing a sequence of questions to elicit information from the interviewee. According to Kotler and Keller (2006) the questionnaire can be defined as a set of questions presented to respondents. It is commonly used to gather data and also very flexible because it could be administered in person, by phone or online. The questionnaire of the study was made up of both close ended and open ended questions. Close ended questions constituted the basis of the structured questions. The open ended questions were generally inserted to provide a more complete picture of the respondents. The study involved one thousand and two hundreds respondents which comprise the total population of workers at selected pharmaceutical industries. One thousand and two hundreds questionnaires were retrieved and analyzed. The results were analyzed from the perception of the respondents. The questionnaire solicited key information from the following variables:

Section A: Personal details

Section B: TQM practices in selected pharmaceutical industries.

Section C: Effectiveness of TQM practices at selected pharmaceutical industries.

Section D: Effect of TQM on organizational performance

Section E: Management view on organizational performance.

3.4 Data Collection Procedure

The researcher assigned two years for the entire data collection exercise. Before the questionnaires were administered, they were pre-tested on some workers to check whether it would help achieve the objectives of the study. It also showed whether the right responses would be provided by the respondents. It did help to clarify ambiguities and uncertainties regarding questions which were asked. After the pre-test the questionnaires were then administered.

3.5 Data Analysis

Analysis is a research technique for making replicable and valid references from data to their context. The researcher searches for structure and pattern regularities in the text and makes inferences on the basis of the regularities (Krippendor, 1980). Quantitative data analysis was used to process the data. For the quantitative analysis Statistical Package for Social Sciences (SPSS version 17) was used to process the data. For the lower version of analysis for the perception of respondents percentages were used to analyse the data. This means that the analysis was done on the content of the data which were collected.

4. Discussions of Results

Primary data was gathered on TQM practices and its effects on organizational performance at Selected pharmaceutical industries in AP and Telangana states. The analysis covered personal details, TQM practices, effectiveness of the TQM practices, effect of TQM on organisational performance, and Management view on organizational performance. The complete data is given in Table No.01.

Table 1: TQM study Details

I. **Personal Details**				
Gender of respondents				
	Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Male	690	57.5	57.5	57.5
Female	510	42.5	42.5	100.0
Total	1200	100.0	100.0	
Educational background of respondents				
Elementary	620	51.7	52.5	52.5
Secondary / Technical	200	16.7	16.9	69.5
Training College	40	3.3	3.4	72.9
Polytechnic/ University	290	24.2	24.6	97.5
Others	30	2.5	2.5	100.0
Total	1180	98.3	100.0	
Missing System	20	1.7		
Total	1200	100.0		
Departments of respondents				
Valid Quality Assurance	820	68.3	68.3	68.3
Marketing	80	6.7	6.7	75.0
Engineering	210	17.5	17.5	92.5
Finance	90	7.5	7.5	100.0
Total	1200	100.0	100.0	
Length of service of respondents				
Valid 1 - 5 years	130	10.8	10.8	10.8
6 - 11 years	220	18.3	18.3	29.2
12 -17 years	160	13.3	13.3	42.5
18 - 23 years	60	5.0	5.0	47.5
24 years and above	630	52.5	52.5	100.0
Total	1200	100.0	100.0	
II. TQM Practices				
Respondents view of Leadership Commitment to the work				
Valid Strongly Agree	570	47.5	47.5	47.5
Agree	560	46.7	46.7	94.2
Neutral	20	1.7	1.7	95.8
Disagree	30	2.5		98.3
Employee involvement in quality decisions				
Valid Strongly Agree	100	8.3	8.3	8.3
Agree	540	45.0	45.0	53.3
Neutral	200	16.7	16.7	70.0
Disagree	600	5.0	5.0	75.0
Strongly disagree	300	25.0	25.0	100.0
Total	1200	100.0	100.0	
Effective Communication				
Valid Strongly Agree	150	12.5	12.5	12.5
Agree	740	61.7	61.7	74.2

Neutral	80	6.7	6.7	80.8
Disagree	150	12.5	12.5	93.3
Strongly disagree	80	6.7	6.7	100.0
Total	1200	100.0	100.0	
Team Work				
Valid Strongly Agree	300	25.0	25.0	25.0
Agree	830	9.2	69.2	94.2
Neutral	20	1.7	1.7	95.8
Strongly disagree	50	4.2	4.2	100.0
Total	1200	100.0	100.0	
System for recognition and appreciation of quality efforts				
Valid Strongly Agree	170	14.2	14.2	14.2
Agree	430	35.8	35.8	50.0
Neutral	230	19.2	19.2	69.2
Disagree	260	21.7	21.7	90.8
Strongly disagree	110	9.2	9.2	100.0
Total	1200	100.0	100.0	
Respondents view on training & development				
Valid Strongly Agree	270	22.5	22.7	22.7
Agree	750	62.5	63.0	85.7
Neutral	40	3.3	3.4	89.1
Disagree	80	6.7	6.7	95.8
Strongly disagree	50	4.2	4.2	100.0
Total	1190	99.2	100.0	
Missing System	10	8		
Total	1200	100.0		
Respondents view on self assessment				
Valid Strongly Agree	180	15.0	15.0	15.0
Agree	910	75.8	75.8	90.8
Neutral	60	5.0	5.0	95.8
Disagree	30	2.5	2.5	98.3
Strongly disagree	20	1.7	1.7	100.0
Total	1200	100.0	100.0	
III. Effectiveness Of TQM Practices				
Is customer satisfaction everybody's business in the organization?				
Valid Yes	1050	87.5	87.5	87.5
No	150	12.5	12.5	100.0
Total	1200	100.0	100.0	
Department which is responsible for product quality in the organization				
Valid No body	50	4.2	4.2	4.2
Quality Control Department	220	18.3	18.6	22.9
Quality Assurance Department	880	73.3	74.6	97.5
TQM Department	30	2.5	2.5	100.0
Total	1180	98.3	100.0	
Missing System	20	1.7		
Total	1200	100.0		
Respondents view on subscription to any quality award system				
Valid Yes	40	3.3	3.6	3.6
No	1070	89.2	96.4	100.0
Total	1110	92.5	100.0	
Missing System	90	7.5		
Total	1200	100.0		
Response on training received on the job				
Valid Yes	990	82.5	86.1	86.1
No	160	13.3	13.9	100.0
Total	1150	95.8	100.0	
Missing System	50	4.2		
Total	1200	100.0		
Respondents' view on whether training received has impacted positively on the work				
Valid Yes	1020	85.0	91.9	91.9
No	90	7.5	8.1	100.0
Total	1110	92.5	100.0	
Missing System	90	8.1		

Total	1200	100.0		
All the resources the respondents need to carry out any improvement on the job are readily available				
Valid Strongly Agree	30	2.5	2.6	2.6
Agree	390	32.5	33.6	36.2
Neutral	180	15.0	15.5	51.7
Disagree	400	33.3	34.5	86.2
Strongly disagree	160	13.3	13.8	100.0
Total	1160	96.7	100.0	
Missing System	40	3.3		
Total	1200	100.0		
IV. Effect Of TQM On Organizational Performance				
Respondents view on reworks done in the departments				
Valid Yes	430	35.8	38.1	38.1
No	700	58.3	61.9	100.0
Total	1130	94.2	100.0	
Missing System	70	5.8		
Total	1200	100.0		
Respondents view on the relationship between them and the organization can be described as satisfactory				
Valid Strongly Agree	90	7.5	7.9	7.9
Agree	780	65.0	68.4	76.3
Neutral	120	10.0	10.5	86.8
Disagree	90	7.5	7.9	94.7
Strongly disagree	60	5.0	5.3	100.0
Total	1140	95.0	100.0	
Missing System	60	5.0		
Total	1200	100.0		
Respondents view on whether they are losing some customers				
Valid Strongly Agree	140	11.7	12.1	12.1
Agree	430	35.8	37.1	49.1
Neutral	380	31.7	32.8	81.9
Disagree	190	15.8	16.4	98.3
Strongly disagree	20	1.7	1.7	100.0
Total	1160	96.7	100.0	
Missing System	40	3.3		
Total	1200	100.0		
Respondents view on reasons why they are losing some customers				
Valid Inadequate Customer satisfaction	50	4.2	8.9	8.9
Preferred Foreign Products	50	4.2	8.9	17.9
Other	190	15.8	33.9	51.8
Higher prices	270	22.5	48.2	100.0
Total	560	46.7	100.0	
Missing System	640	53.3		
Total	1200	100.0		
Respondents view on which of these Quality functions will help improve upon organizational performance				
Valid Quality Control	40	3.3	3.7	3.7
Quality Assurance	370	30.8	33.9	37.6
TQM	450	37.5	41.3	78.9
All of the above	230	19.2	21.1	100.0
Total	1090	90.8	100.0	
Missing System	110	9.2		
Total	1200	100.0		
Respondents view on number of reworks done in a year				
Valid 3 - 5 times	120	10.0	26.1	26.1
1-2 times	340	28.3	73.9	100.0
Total	460	38.3	100.0	
Missing System	740	61.7		
Total	1200	100.0		
Respondents view on the loss rate per annum				
Valid about 1%	550	45.8	82.1	82.1
about 3%	20	1.7	3.0	85.1
about 4%	30	2.5	4.5	89.6
about 5%	70	5.8	10.4	100.0
Total	670	55.8	100.0	

Missing System	530	44.2		
Total	1200	100.0		
V. Senior Staff View On Organizational Perfromance				
Respondents' view on customer complaints				
Valid Yes	180	81.8	81.8	81.8
No	40	18.2	18.2	100.0
Total	220	100.0	100.0	
Respondents' view on number of customer complaints received for the past two years				
Valid 1-4	180	81.8	81.8	81.8
5-8	40	18.2	18.2	100.0
Total	220	100.0	100.0	
Respondents' view on whether some customers have stopped buying from the organization				
Valid Yes	170	77.3	85.0	85.5
No	30	13.6	15.0	100.0
Total	200	90.9	100.0	
Missing System	20	9.1		
Total	220	100.0		
Respondents' views on the reasons why some customers have stopped buying from the organization				
Valid High Prices	140	63.6	82.4	82.4
Poor customer relationship	30	13.6	17.6	100.0
Total	170	77.3	100.0	
Missing System	50	22.7		
Total	220	100.0		
Respondents view on whether the organization has lost some USFDA audits				
Valid Yes	220	100.0	100.0	100.0
Respondents' reasons why the organization lost some major audits				
Valid GMP Practices	100	45.5	45.5	45.5
GLP Practices	120	54.5	54.5	100.0
Total	220	100.0	100.0	
Respondents' view on the increase in volume of sales for the last two years compared to those previous years				
Valid strongly Agree	40	18.2	18.2	18.2
Agree	160	72.7	72.7	90.9
Disagree	20	9.1	9.1	100.0
Total	220	100.0	100.0	

5. Conclusions

The purpose of the research was to assess TQM practices and its effect on organizational performance at selected pharmaceutical industries, in the southern Region of India. It is noteworthy that some of the recommendations made can help implement the TQM practices which could be employed to bring improvement in organizational performance at selected pharmaceutical industries and other pharmaceutical companies in India. Primary data was collected by the use of questionnaire from a population of 1200 respondents were retrieved from the respondents and analyzed. The objectives of the study were to explore the degree of effectiveness of TQM practices in selected pharmaceutical industries, to analyse the extent to which TQM practices affect organizational performance and to identify the challenges involved in implementing TQM practices at selected pharmaceutical industries, India.

5.1 Personal Details

The analysis showed that there were more males than females working in selected pharmaceutical industries, about 44.2% of the respondents are nearing the retiring age of 60 this could have some effect on productivity especially if dealing with labour intensive work like manufacturing. It could also lead to an expensive learning curve when most of the staff go on retirement around the same period. 51.7% of the respondents had attained either Elementary and 24.6% were graduates from the polytechnics or the universities, this indicates that the company is doing well to employ skill labour to work with however there are still too many staff that are middle school leaving certificate holders which if care is not taken could lead to some challenges with documentation and communication. 52.5% of the respondents had worked with the company for more than 24 years. This indicates a low labour turnover which implies management could be doing something right with the human resource aspects of the TQM practices.

5.2 TQM Practices

The findings show clearly that TQM practices in selected pharmaceutical industries includes; leadership commitment to work, employee involvement in quality decisions, effective communication, team work, system for recognition and appreciation of quality efforts, training and development and self assessment.

Majority of the respondents agreed that all the above mentioned TQM practices were being practiced. Generally it is perceived that majority of the workers agreed that the companies has some TQM practices in place.

5.3 Effectiveness of TQM Practices

The study explored the degree of effectiveness of TQM practices at selected pharmaceutical industries. Majority of the

respondents agreed that customer satisfaction was every body‘s business in the organization. Most of the respondents disagreed that they had subscribed to any quality award system. This implies TQM is not being implemented to the highest level. Majority of the respondents said they have received some training. Nearly all of them agreed that the training and development received had positively imparted on the job. This is a good practice of TQM. About half of the respondents indicated that they don‘t receive all the necessary resources required to carry out any improvement on the job. This goes a long way to undermine the commitment of leadership to quality. On the whole the researcher found out that though there were some TQM practices and these practices were not effectively practiced.

5.4 Effect of TQM Practices on Organizational Performance

Further the majority of the respondents said they were satisfied with their employer in terms of the relationship which exists between them. This again emphasises the fact that management was treating the employees well however since it is not overwhelming majority of the respondents which shared that view management could do more to make it effective so that most of the respondents would be satisfied. Nearly half of the respondents agreed that the company was losing some of its customers and most of these respondents were of the view that the reason was due to high prices of the company products. It could also mean that some customer concerns have not been properly addressed. This could mean that some TQM practices are not effective. When this was probed further some respondents were of the view that the reasons could be due to high prices, preference for foreign products and inadequate customer satisfaction. These could be proof that the existing TQM practices are not adequately addressing the major concerns which affect organizational performance.

5.5 Analysis of Senior Staff View on Organizational Performance

On the senior staff views on organizational performance as well as some challenges that the organization was experiencing, it is clear from the findings that most of the respondents were of the view that they receive customer complaints however these complaints were not frequent. Most of them indicated that some customers have stopped buying from their companies. These respondents concluded that the reasons were due to higher prices and poor customer relationships. The respondents continued to state that they have lost major audits due to poor GMP and GLP practices, however sales have been good compared to the last two years.

They concluded that if management could carry out the following changes the firm could improve upon its performance

- The need for modern equipment.
- Diversification of key portfolio in other to spread cost.
- The need to improve salaries of employees.
- Reduction of cost of production.
- Trust amongst staff to improve team work
- Good GMP and GLP practices

The study sought to assess the TQM practices and its effect on organizational performance at selected pharmaceutical industries. The study concluded that some TQM practices exist in every company. Another conclusion which was drawn from the findings was that the TQM at selected pharmaceutical industries was not being implemented to the highest level.

Again management inactions undermine leadership commitment to quality and render TQM practices ineffective. For example the necessary resources required to carry out quality improvement were not readily available.

Also majority of the staff were satisfied with working with selected pharmaceutical industries, however the company was losing drug approvals and some customers due to poor customer relationships, uncompetitive pricing and poor practices.

It was also revealed that some challenges were encountered in the implementation of TQM notable amongst them were ; lack of modern equipment, lack of diversification of key portfolio in other to spread the overhead cost, high cost of production, lack of trust amongst staff to improve team work and good GMP and GLP practices. In all the study established the fact that if TQM practices are employed effectively in selected pharmaceutical industries, it could improve upon organizational performance.

6. References

1. Dale BG. Managing Quality‖, Blackwell Business, Oxford, 1999.
2. Dhalla RS. Proceedings of the 2010 International Conference on Industrial Engineering and Operations Management Dhaka, Bangladesh, 2010.
3. Kotler P, Armstrong G. Principles of Marketing, 11th Ed., Pearson Education, upper Saddle River, New Jersey: Prentice-Hall Inc, 2006.
4. Krippendor K. Content analysis. An introduction to its methodology. Newbury Park, CA: Sage, 1980.
5. Mohanty RP, Lakhe RR. Understanding TQM, Production planning and control. 1994; 5(5):426-441.
6. Oakland JS. Total Quality Management: The Route to Improving Performance, Butterworth-Heinemann, Oxford, 1993.
7. Rubin A, Babbie E. Research methods for social work (4th ed.). Belmont, CA: Wadsworth/Thomson Learning, 2001.