

# TQM PRACTICES IN INDIAN PHARMACEUTICALS: AN APPRAISAL

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**ABSTRACT**

*In this paper, TQM practices used in Indian pharmaceutical sector is studied. A brief introduction to total quality management and literature review is presented in first two sections the paper. The methodology and tools of study were discussed. In this data is collected with the help of questionnaire which was pretested. Factor analysis was applied to reduce the data and to find out the various TQM practices in Indian pharmaceutical sector.*

**Key Words :** Quality, TQM, Pharmaceutical Industry, GMP

**Introduction**

Quality of product and services is the main concern of companies now a days, as now customers are more and more concern about the quality, when it is the matter of pharmaceutical companies, quality becomes more serious issue as it is concerned with humanity.

In total quality management (TQM) the applications of quality management principles are applied to all aspects of the business. Quality is not just product/service quality but it is the quality of the whole organization, including sales, finance, personnel and all other functions.

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TQM is very important for pharmaceutical industries to produce the better product and ensure the maximum safety of healthcare system and also protect waste of money for both government & individual consumers. Pharmaceuticals continue to have an increasingly prominent role in health care (Shanmugasundaram and Vikram, 2015).

In pharmaceutical industry, the quality is a measure of high degree of managerial, scientific and technical sophistication. This measure of quality in pharmaceutical industry is similar to two accepts of quality management 'soft' and 'hard' TQM as discussed in previous section. From the above discussion on TQM, it can be said that two Soft and Hard TQM are equally important for pharmaceutical industries too.

In pharmaceutical industry quality can be achieved by quality management system (QMS). For pharmaceuticals Good Manufacturing Practices (GMP) is QMS system, which is regulated by government.

Conventional pharmaceutical manufacturing is generally accomplished using batch processing with laboratory testing conducted on collected samples to evaluate quality. This conventional approach has been successful in providing quality pharmaceuticals to the public. But today there are significant opportunities available to improve pharmaceutical development manufacturing and quality assurance through innovation in product and process development, process analysis and process control.

GMP refers to the good manufacturing practice regulations promulgated by US Food and Drug Administration (USFDA) and various other countries regulation authorities. GMP regulations require a quality approach to manufacturing, enabling to minimize contamination, mix-ups and errors (Bhusari et al). GMP sometimes referred as cGMP, where 'c' stands for 'current'.

GMP includes three steps, first to set the standards, second to train the people about these standards and then third is to control through audit. GMP regulations are different for different dosage form and need to implement accordingly. The general consideration in GMP includes i.e general provisions, organization and personnel (responsibility, qualification, responsibility and consultants), building and facilities (design, ventilation, sanitation, sewage, washing etc), Equipment (design, size, automation), components and containers, production and process control (written procedure, sampling, testing), packaging and labeling, holding and distribution, laboratory control, records and reports. (Bhusari et al)

Pharmaceutical Industry should 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).

The Indian pharmaceutical industry is one the major manufacturing industry, which is third largest in terms of volume and 13<sup>th</sup> largest in terms of value in world. Indian is one of the major producers of generic medicine, accounts for 20 per cent global exports in terms of volume. At present over 80 per cent of the antiretroviral drugs used for AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical firms (www.ibef.org).

India is major destinations for low-cost production which in turn helps manufacturing for exports. Pharmaceutical companies like Sun Pharmaceutical Industries Ltd, Cipla Ltd, Dr. Reddy's Laboratories Ltd, Lupin Ltd, Zydus Cadila Ltd and Wockhardt Ltd, have accounted for 33% of the country's total exports, have emerged as world leaders in low-cost innovation and production.

### Literature Review

Wilkinson & Willmott, 1994 suggested that new firms who are adopting TQM for the first time are half-hearted and partial towards Soft TQM factors, as managers seek a quick result to satisfy short-term goals. They emphasize more on the hard factors measurement and control aspects of TQM;

leading to negligence of soft side which is more concerned with people includes practices like culture, training, teamwork and employee participation.

Powell (1995) considered TQM as strategic tool for future resource. He reviewed TQM as competitive advantage. He identified that TQM success depends on some factors i.e. open organization, executive commitment and employee empowerment. It is less depends on Hard TQM factors i.e. benchmarking, training, flexible manufacturing. He identified the significance of Soft TQM aspect like employee empowerment, commitment, and involvement for success of Hard TQM factors.

Mann and Khoe (1995) identified the factor implementing and success of TQM. TQM is a philosophy that is used for long term business goals. They used the term quality critical organizational characteristic (QCOC) to describe a characteristic that influences the effectiveness of a quality practices. They divided QCOC in two categories primary and secondary factors. Organizations should undertake a thorough analysis of QCOCs before implementing TQM. There is a complex relation between organizational characteristics and quality activities. Approach for TQM should be flexible which can be changed from time to time according to requirement.

Joseph., Rajendran & Kamalanabhan (1999) presented a instrument for measuring TQM practices in Indian manufacturing organizations. in their research they found that there are ten factors which are critical for TQM implementation in Indian organizations. These ten practices are Organizational commitment, Human Resources management (HRM), Supplier Integration, Quality policy (QP), Product design, Role of quality department, Quality information systems, Technology utilization, Operating procedures and Training.

Zhang (2000) also presented an instrument for TQM implementation in Chinese manufacturing companies. He identified eleven factors that are critical for the TQM implementation in Chinese manufacturing companies, these factors are Leadership, Supplier quality management, Vision and plan statement, Evaluation, Process control and improvement, Product design, Quality system improvement, Employee participation, Recognition and reward, Education and training and Customer focus.

Samat, Ramayah and Saad (2006) in a study in developing countries explored the relationship between TQM practices and market orientation. They have selected eight practices related to TQM like Management Support & Commitment, Employee Involvement, Employee Empowerment, Information & Communication, Training & Education, Customer Focus and Continuous Improvement. In these factors information and communication showed the major impact on service quality as compared to other six elements, because these are the only practices which in gathering information about the customer in a service organization. Customer focus and employee empowerment also affect TQM. All three (TQM) practices, customer focus and service quality has shown the positive relation with each other.

Chand and Katou (2007) have examined the effect of HRM practices on organizational performance in Indian hotel industry, specially three star and five star hotels. Hotel performance is mostly influenced by size and type of hotel. They have selected eight HRM practices recruitment and selection, manpower planning, job design, training and development, quality circle, and pay systems. Improvement in HRM practices can increase competitive advantage to a greater extent.

Kakkar and Narang (2007) recommended a TQM model for Indian organization. They also tried to find out the effect of TQM implementation on organizational performance. They studies TQM practice as contributing variable and organizational performance as contribution variable. Contributing variables are i.e. Leadership, Top Management Commitment, Quality as a Policy, People Management and Training, Supplier Development, Team Building and Problem Solving, Communication and Feedback , Resources, Planning Conservation and Utilization, Product Design, .Resources Value Addition Process, Systems, Tools and Techniques. Contribution variable are i.e Product Quality, Customer Satisfaction, Market Performance, Employees Satisfaction, Business Results, Cost and Waste Reduction, Safety, Productivity Improvement and Impact on Society. Team building, customer focus, people involvement and operation efficiency are four important pillar of TQM implementation in Indian organizations.

Singh and Dalla (2010) studied the effect of TQM on the performance of Indian pharmaceutical industry. Pharmaceutical industry is heavily regulated. Their study is based on pilot study which is part of their PhD research. Main factors that affect implementation of TQM are Top Management Commitment, Leadership, Quality Management, People Management and Training, Customer Focus and Supplier Quality. To ensure quality and safe products, pharmaceutical companies should use Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and their In- house Standard Operating Procedures (SOPs).

Poongothai et al (2011) in their study on two pharmaceutical companies in Chennai found that TQM increases the workers participation and decrease the rework much. TQM principles showed a high correlation with employee morale, cost of production and reduced number of defects. TQM implementation is not only for growth of organizations, but it is must for its survival in this competitive world.

Al-Qudah (2012) studied the impact of total quality management practices on competitive practices of pharmaceutical manufacturing companies in Jordan. Their study focus on the impact of total quality management practices in Jordan pharmaceutical companies. Competitive advantage of organization acts a weapon for fighting against the competition. There is strong relationship between competitive advantage and customer focus. And a moderate relationship exists between people management, information

analysis and competitive advantage. A weaker relationship exists between leadership and competitive advantage. In general TQM act as a tool for increasing the competitive advantage. It increases the competitive advantage.

Inoue and Yamada (2012) tried to find out critical factors for process improvement in pharmaceutical improvement. Project leader are interviewed separately for the improvement factor. They identified factors as management support and commitment, cooperative culture, shared goals, flexible resource allocation, automation, project scheduling, standardization, steps for improvement, cross-organizational activities, data-driven approaches, and proactive participation of the employees. Those identified by project leaders included project scheduling, automation, flexible resource allocation, standardization, and process improvement methodology, which were also extracted as the context for the key scenario for cross-organizational process improvement.

Psomas, Vouzas and Kafetzopoulos (2014) identified that both Soft and Hard TQM practices are used management system in food industry. Various benefits has arrived if these practices are implemented such as quality improvement, employee benefits, customer satisfaction and improved business performance. But out of these hard and Soft TQM practices, soft TQM practices are in leading role and Hard TQM practices in supporting role.

Kanapathy et al (2017) in their study of Soft and Hard TQM practices on innovation performance, they identified the Soft and Hard TQM practices from the literature. Soft TQM practices i.e. top management support, Employee Involvement and employee training. And Hard TQM practices i.e. quality information, usage of information, supplies quality, and customer orientation. They suggest that Soft TQM factors shows significant effect on innovation performance while Hard TQM factors are insignificant towards it. Adopting new technology can improve their processes.

Kumar & Prasad (2017) studied the TQM practices in Indian pharmaceutical in Andhra Pradesh and Telangana region. Major Soft TQM practices in Indian pharmaceutical 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. Out of these practices some are implemented and some are not properly implemented. Existing practices of TQM are not influencing the organizational effectiveness

Owusu and Duah (2018) studied TQM as competitive advantage in mobile and telecommunicating industry. He concludes that if organizations focus on TQM as internal Strategy, in reduce variations, waste and cost of production. Organization can gain cost competitiveness over the others. But the strategy development and stake holder involvement must be included to foster performance.

### **Objectives of Study**

This research paper is carried out with following objectives:

1. To find status of quality practices in Indian pharmaceutical industry.
2. To find the main practices of TQM used by Indian pharmaceutical industry.

### Research Methodology

#### Research Design and instrument:

The exploratory research design is used in this paper. Primary data is used for the study, which is collected with help of well-structured and pre-tested questionnaire. Questionnaire was developed on a likert scale on five point scale from 1 to 5 (which moves from “not at all” to “large extent”) for the first two parts of the questionnaire i.e. Soft and Hard TQM practices.

#### Sampling Technique:

The universe for the present study comprised of employees of pharmaceutical companies (Indian, MNCs, public, private companies) especially working in production, quality assurance and control, research and development departments etc. List of pharmaceutical companies was taken from NPPA (The National Pharmaceutical Pricing Authority) and other government sites (<http://pharmaceuticals.gov.in/>, <https://nhp.gov.in/drugs-and-pharmaceuticals/>) and

manufacturing associations of pharmaceuticals companies ([www.ipapharma.org/](http://www.ipapharma.org/), <https://www.idma-assn.org>, <https://www.indiaoppi.com>). There are total around 5000 companies in India; total 135 companies are selected from northern region (Annexure). Snow ball sampling was used to select the companies for collection of data. Total questionnaires 620 were distributed among the respondents by both offline and online. Out of these 620 questionnaires about 546 are received back. Out of these 546 questionnaires 508 are found useful and completely filled. Other 38 questionnaire are rejected because of incomplete information.

#### Statistical Tools for Analysis:

The collected data was properly classified and tabulated. The data was also checked for reliability. Further the data was analyzed with the help of various statistical tools i.e. means, percentages and factor analysis.

#### Data Analysis and Interpretation

Demography is the study of population characteristic. Commonly used demographic characteristics are age, income, education, experience, gender etc.

**Demographic profile of respondent organizations:** The demographic characteristics of organization used in study are presented in table 1.

**Table 1 : Demographic profile of companies**

Variables	Categories	Frequency	Percent	Valid Percent	Cumulative Percent
Origin of company	MNC	139	27.4	27.4	27.4
	Indian	369	72.6	72.6	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
Ownership	Public	184	36.2	36.2	36.2
	Private	324	63.8	63.8	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
Turnover (in crores)	1-100	157	29.9	30.5	30.5
	101-500	124	24.4	24.9	55.4
	501-1000	78	14.4	14.7	70.1
	More than 1000	149	29.3	29.9	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>		

(Source: Primary data)

**Demographic profile of respondents :** The demographic profile of respondent is given in table 2

**Table 2 : Demographic profile of respondents**

Variables	Categories	Frequency	Percent	Valid percentage	Cumulative percentage
Gender	Male	402	79.1	79.1	79.1
	Female	106	20.9	20.9	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
Age (in years)	Under 25	72	14.2	14.2	14.2
	25-30	255	50.2	50.2	64.4
	30-40	130	25.6	25.6	90.0

	40-50	44	8.7	8.7	98.6
	More than 50	7	1.4	1.4	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
<b>Educational Qualification</b>	Under Graduate	5	1.0	1.0	1.0
	Graduate	148	29.1	29.1	30.1
	Post Graduate	350	68.9	68.9	99.0
	Any other	5	1.0	1.0	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
<b>Experience (in years)</b>	0-3	111	21.9	21.9	21.9
	3-7	140	27.6	27.6	49.4
	7-10	121	23.8	23.8	73.2
	More than 10	136	26.8	26.8	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	
<b>Department</b>	Quality control and assurance	184	36.2	36.2	36.2
	Production	132	26.0	26.0	62.2
	Marketing	79	15.6	15.6	77.8
	Customer relation	18	3.5	3.5	81.3
	Any other (purchasing, packaging etc.)	95	18.7	18.7	100.0
	<b>Total</b>	<b>508</b>	<b>100.0</b>	<b>100.0</b>	

(Source: Primary Data)

Various TQM practices in pharmaceutical companies: the questionnaire is subjected to factor analysis, from where nine

factors of Soft TQM practices are identified which are presented in table 3.

**Table 3 : Soft TQM practices in Indian pharmaceutical Industry**

Factor No.	Factor Name	Number of Variables loaded	Eigen Value	Percentage of Variance
Soft TQM 1	Rewards and Motivation	12	25.135	41.205
Soft TQM 2	Supplier performance Analysis	9	3.388	5.554
Soft TQM 3	Training and education	7	2.863	4.693
Soft TQM 4	Top Management Commitment	8	1.817	2.979
Soft TQM 5	Team work and feedback	7	1.675	2.746
Soft TQM 6	Communication and information	4	1.384	2.269
Soft TQM 7	Employee empowerment	4	1.268	2.079
Soft TQM 8	Employee participation	3	1.187	1.946
Soft TQM 9	Customer orientation	3	1.109	1.819
	<b>Total</b>	<b>57</b>		<b>68.686</b>

(Source: Primary data)

From the table it is clear that data is reduced to 11 factors, but there are only one variable on factor 10 and 11 so these two factors will not be used in further analysis. The very first factor includes 12 variables (table 3), named as **Employee motivation and Rewards**, the second factor include nine variables named as **Supplier Performance and Analysis**, third factor includes seven variables named as **Training and Education**, fourth factor includes eight variables, named as

**Top Management Commitment**, fifth factor includes seven variables, named as **Teamwork and Feedback**, the sixth factor includes four variables, named as **Communication and information**, the seventh factor includes four variables, named as **Employee Empowerment**, the factor eight includes three variables, named as **Employee Participation** and factor nine also includes three variables, named as **Customer Orientation**.

Table 4 : The various Hard TQM practices in Indian pharmaceuticals

Factor No.	Factor Name	Number of Variables loaded	Eigen Value	Percentage of Variance
Hard TQM 1	Operating and Manufacturing process	17	17.293	50.804
Hard TQM 2	Bench marking and SPC	8	2.110	6.205
Hard TQM 3	Audit and inspection	6	1.289	3.791
	<b>Total</b>	<b>31</b>		<b>63.850</b>

(Source: Primary data)

From the table it is clear that data is reduced to four variable, but there are only one variable on factor four, so this factor will not be used in further analysis. Factor one contains 17 variables, named as **Operating and Manufacturing Process**, factor two contains eight variables, named as **Benchmarking and SPC** and factor three contains six variables, named as **Audit and Inspection**.

### Conclusion

From the data analysis, it is clear that in almost all the companies following the both Soft and Hard TQM practices in their organizations. In case of Soft TQM practices, most commonly used practices are Employee motivation and Rewards, Supplier Performance and Analysis, Training and Education, Top Management Commitment, Teamwork and Feedback, Communication and information, Employee Empowerment, Employee Participation and Customer Orientation. In case of Hard TQM practices, most commonly practices are Operating and Manufacturing Process, Benchmarking and SPC and factor and Audit and Inspection. These TQM practices help the companies to gain the competitive advantage over the global firms and Indian pharmaceutical industry is one of growing industry at global level.

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