

Drivers of Quality Management in Selected Pharmaceutical Companies in Tamil Nadu : A Chi-Square Approach to Validation

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Abstract

A quality management system is a system used to manage and evolve a globally competitive business, irrespective of the size of the business. A quality system is critical in the pharmaceutical industry since the products directly impinge on the well-being of the consumer. In this backdrop, the present study has examined the factors influencing the quality system management in selected pharmaceutical firms in Tamil Nadu, and also examines the relationship between selected factors and the level of the quality management system. Primary data collected in this study was analyzed using chi-square test that represents a useful method of comparing experimentally obtained data with those expected theoretically. The study concluded that of the ten variables tested, five variables namely, capital investment, percentage investment on quality control, percentage operating expenditure on quality control / assurance, ISO certification, and vendor evaluation influenced the level of the quality system in case of small firms producing pharmaceutical products, and in the case of medium and large firms, only three variables namely, percentage operating expenditure on quality control / assurance, personnel cost, and vendor evaluation influenced the level of the quality system in the study area. Percentage operating expenditure on quality control / assurance and vendor evaluation impacted and influenced the level of the quality system, irrespective of the size of the firm, that is, small, medium, or large firms in the study area.

Key words: product quality, quality management, pharmaceutical, chi-square

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Good is no longer good enough. To survive in today's competitive environment, you need to excel. Quality is never an accident. Quality is not a subjective feeling, but is an objective fact. It is always the result of high intentions, sincere efforts, intelligent direction, and skillful execution. In today's competitive scenario, for firms to survive in the market place, they need good quality management system. This is irrespective of the size of the business - large, medium, or small. The job of quality management is not just advising a sampling plan for the acceptance / rejection of the incoming materials and controlling manufacturing process conditions. It is, in fact, a condition at every stage of the company's activity, involving the combined efforts of various departments such as product/process development, purchase, production, inspection and others, in different phases, with a view to achieve the desired quality of the end product. More so, a quality system is critical in the pharmaceutical industry since the products directly impinge on the well-being of the consumer and sometimes patrol the boundary between life and death. The healthcare system in any country is important since health is one of the three major components that determine the Human Development Index as shown in various human development reports between 1990 and 1997 of the United Nations Development Program.

Literature Review

The Indian pharmaceutical industry is the world's third-largest in volume terms (Ramsurya, 2010). Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Annual Report 2012 estimated the turnover of India's

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pharmaceuticals industry in 2009 at US\$21.73 billion and the domestic market at US\$12.26 billion, and the annual report of the National Pharmaceutical Pricing Authority (2010) also indicated that the industry was growing at 9.38 % for the year ending March 2010, employing 3,53,962 people. India Brand Equity Foundation (2013) estimated that the Indian pharmaceutical market will grow at a compound annual growth rate (CAGR) of 14-17% in between 2012 and 2016, making India among the top five pharmaceutical emerging markets of the world.

Tamil Nadu is one of the leading states in India and is the fifth largest pharmaceutical producing state in the country (IBEF, 2013) in the production of drugs. At present, 1625 drug firms are functioning in Tamil Nadu as per records obtained from various reports of Tamil Nadu Pharmaceutical Manufacturer's Association, Chennai. The industry's output consists of bulk drugs and formulations. Out of the total output, about 80% constitutes formulations and 20% constitutes bulk drugs. About 35% of the output is being exported, the rest is consumed domestically. Out of the total exports, bulk drugs account for 60% and the remaining are formulations. The secondary data has been obtained from the annual report of companies, publications of the Organization of Pharmaceutical Producers on India (OPPI), and the Indian Drug Manufacturer's Association (IDMA) data bank. Apart from this, data was also gathered from journals, magazines, and newspapers.

Every firm, depending on its size and resource capabilities, adopts different processes for quality management. Total quality management (TQM) is seen as a tool to improve organizational performance in both large and small organizations in any part of the world. Literature review identified authors like Anderson and Sohal (1999), Evans (1996), and Samson and Terziovski (1999) who conducted such studies in developed countries. Most of the studies have been based on large firms and in developed countries. Some authors (Adam 1994; Anderson & Sohal, 1999; Powell, 1995) have carried out studies to determine the importance of management practices on organizational performance. The concept of quality has been a concern for most businesses. Vokurka (2001) in his article stated, "global competitiveness is a reality, and quality is the key to winning in the marketplace. By itself, quality may not guarantee success, but it is difficult to compete without it. And like most other competitive factors, the standards of quality are constantly rising" (p. 363). Quality was defined by Karapetrovic and Willborn (1997) as "the ability of a product to satisfy stated or implied requirements" (p. 287). According to Wessel and Burcher (2004), "quality management in general deals with permanently redirecting a company's macro and micro operations towards the needs of internal and external customers" (p. 264).

Dow, Samson, and Ford (1999) concluded that the relationship between quality practices and superior quality outcomes is a fundamental and defining element of the whole concept of quality management. The results of a research by Zhang and Xia (2013), who examined the relationship between effective quality management and firm performance suggested that quality is still critical to achieving long-term competitive advantage, and firms who continuously improve their quality continue to reap rewards by way of sales and financial performances exceeding those of their competitors. In the wake of interest in and attention to quality, total quality management (TQM) concepts emerged in the 1950s in Japan, kicked off by Dr. Edwards Deming (Garvin & March, 1990). Al-Bourini, Al-Abdallah, and Abou-Moghli (2013) defined TQM as the methodological and organized way to guarantee the flow of activities that were pre-planned, and is the optimal method to prevent and avoid problems by encouraging good behaviors, and through the best utilization of the control methods. According to Jayaraman (2013), TQM led to the Business Excellence (BE) movement, which was started in the USA in 1987 through the declaration of the Malcolm Baldrige National Quality Award (MBNQA) for excellently performing U.S. companies, which was a logical extension of the TQM wave that swept Japan and other countries.

Much of the research literature on the relationship between quality management practices pertains mostly to the developed world. In developing countries like India, the study of quality management practices is scanty, particularly in the pharmaceutical sector, on account of predominance of small firms, which lack resources, are usually not quality conscious, are privately owned, and do not come under the purview of Drug Price Control Order for the formulations made by them. However, the real reason is the companies' emphasis on profits than on more important values relating to quality, communication, decision making, feedback, discipline, and delegation.

Objectives of the Study

The present study was undertaken after reviewing the literature available and considering the research gaps with

respect to quality system management in the pharmaceutical sector in India. In the present study, an attempt was made to analyze ten factors that influence the quality systems of the selected pharmaceutical units. The level of the quality system was determined by the score values calculated for 30 factors in an earlier study conducted by us (Swaminathan & Balasubramanian, 2013) by adopting scaling technique, namely Likert-type scale. The ten influencing factors selected for this study are - capital structure, capital investment, percentage expenditure on quality control, operating expenditure, percentage operating expenditure on quality control / assurance, firm's turnover, personnel cost incurred on quality systems, ISO certification, area of selling, and vendor evaluation. The firms were classified as small, medium, and large as defined in the Industries Regulation Act. The data and the analysis are presented as :

- (1) Relationship between the selected factors and the level of the quality system for small pharmaceutical units.
- (2) Relationship between the selected factors and the level of the quality system for medium and large pharmaceutical units.

Data and Methodology

For the purpose of selecting a sample for the present study, four regions in Tamil Nadu namely, Chennai, Coimbatore, Madurai, and Trichy that account for more than 70% of the universe in Tamil Nadu were chosen. After obtaining a list of 658 functioning pharmaceutical firms from the respective district industry centers, a total of 150 pharmaceutical firms were selected by adopting a proportionate probability random sampling method. 102 out of 150 were small firms, and 48 were large and medium firms. The definition of small, medium, and large firms was as per The Industries (Development and Regulation) Act 1951, Govt. of India. The selected firms were contacted in person and the objectives of the study were explained to them and their co-operation was sought. A tentative interview schedule was prepared and administered to 20 firms on a pilot basis in order to test the instrument and reliability. The pilot survey helped us to review and modify the instrument suitably. A modified final interview schedule was then drawn, and the instrument was administered by conducting personal interviews in between August 2009 - July 2010.

↳ **Framework of Analysis :** In a study by Swaminathan and Balasubramanian (2013), the level of a quality system was determined by the score values calculated for 30 factors by adopting a scaling technique, namely Likert-type scale (Selltitz, Jahoda, Deutsch, & Cook, 1962). This study was adopted, and the level of the quality system was classified into three categories, namely high, medium, and low for analytical purposes. While the score values $\geq \bar{X} + SD$ and the score values $\geq \bar{X} + SD$ were classified as high and low respectively, the score values between $\bar{X} + SD$ and $\bar{X} - SD$ were classified as being of a medium level quality system. $\bar{X}$ and SD are the arithmetic mean and standard deviation from the score values of 102 and 48 small, medium, and large pharmaceutical units respectively out of a total sample of 150 firms.

↳ For Small Firms

$(\bar{X} + SD) = 68 + 12.72 = 80.72$ and above = High,
 $(\bar{X} - SD) = 68 - 12.72 = 55.28$ and below = Low,
 $(\bar{X} - SD)$ to $(\bar{X} + SD) = 55.28$ to 80.72 = Medium.

Table 1. Level of Quality System of Selected Pharmaceutical Firms

Sl.No.	Level of Quality System	Small Firms	Medium & Large Firms
1.	High	18 (17.65)	28 (58.33)
2.	Medium	26 (25.49)	16 (33.33)
3.	Low	58 (56.86)	4 (8.33)
	Overall	102 (100.00)	48 (100.00)

✍ For Medium and Large Firms

$(\bar{X} + SD) = 98 + 16.26 = 114.26$ and above = High,

$(\bar{X} - SD) = 98 - 16.26 = 81.74$ and below = Low,

$(\bar{X} - SD)$ to $(\bar{X} + SD) = 81.74$ to 114.26 = Medium.

The results are given in the Table 1. From our earlier study (Swaminathan & Balasubramanian, 2013) and Table 1, it emerged that out of 102 small firms, less than half of the firms, that is, 43.04% (54) fell under high and medium quality system management, whereas a majority (56.86% ; 58) had low level quality systems. In case of medium and large sized firms, however, it was the reverse, and more than half, that is, 58.33% or 28 out of 48 firms were under the category of high level quality systems, and only 8.33% of the firms (4) fell under low level quality systems, with the balance being under medium level quality systems. In the current study, in order to examine the relationship between the selected factors and the level of quality system, the chi-square test (Kothari, 1978; Malhotra & Dash, 2010) was applied. The chi-square test represents useful methods of comparing experimentally obtained data with those expected theoretically. The chi-square value is calculated by adopting the following formula:

$$\text{Chi-Square} = \sum \frac{(O - E)^2}{E} \text{ with } (r - 1)(c - 1) \text{ degrees of freedom.}$$

Where,

O = Observed frequency

E = Expected frequency

$E = \frac{\text{Row Total} \times \text{Column Total}}{\text{Grand Total}}$

c = Number of columns,

r = Number of rows

In this study, the null hypothesis formulated was that the quality system is independent of the 10 selected factors. The calculated value of chi-square was compared with the table value of chi-square for the given degree of freedom at 5% level of significance. If at the stated level, the calculated value (C.V.) is less than the table value (T.V), the null hypothesis is accepted; otherwise, it is rejected.

Table 2. Capital Structure of Firms (Small Firms)

Sl. No.	Sector	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Private	13 (72.22)	20 (76.92)	51 (87.93)	84 (82.35)	Calculated Value CV	2.9351
2.	Public	5 (27.78)	6 (23.08)	7 (12.07)	18 (17.65)	Table Value TV at 5 %	5.991
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)	Degrees of Freedom	2

Table 3. Capital Investment (Small Firms)

Sl. No.	Capital Investment (₹ in crores)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 1 crore	5 (27.78)	11 (42.31)	11 (18.97)	27 (26.47)	Calculated Value CV	14.5605
2.	1 - 2 crores	8 (44.44)	6 (23.08)	37 (63.79)	51 (50.00)	Table Value TV at 5 %	9.49
3.	2 crores and above	5 (27.78)	9 (34.61)	10 (17.24)	24 (23.54)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 4. Percentage of Investment on Quality Control (Small Firms)

Sl. No.	Percentage of Investment on Q.C. to the Total Capital in Investment	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 5	7 (38.89)	16 (61.54)	9 (15.52)	32 (31.37)	Calculated Value CV	21.6547
2.	5 - 10	6 (33.33)	5 (19.23)	38 (65.52)	49 (48.04)	Table Value TV at 5 %	9.49
3.	10 and above	5 (27.78)	5 (19.23)	11 (18.96)	21 (20.59)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 5. Operating Expenditure (Small Firms)

Sl. No.	Operating Expenditure (₹ in lakhs)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 25	8 (44.44)	6 (23.08)	14 (24.14)	28 (27.45)	Calculated Value CV	5.1955
2.	25 - 50	6 (33.33)	15 (57.69)	39 (67.24)	60 (58.82)	Table Value TV at 5 %	9.49
3.	50 and above	4 (22.23)	5 (19.23)	5 (8.62)	14 (13.73)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 6. Percentage of Operating Expenditure on Quality Control / Assurance (Small Firms)

Sl. No.	Percentage of Operating Expenditure on Quality Control / Assurance	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 5	3 (16.67)	11 (42.31)	14 (24.14)	28 (27.45)	Calculated Value CV	23.6869
2.	5 - 10	6 (33.33)	10 (38.46)	40 (68.96)	56 (54.90)	Table Value TV at 5 %	9.49
3.	10 and above	9 (50.00)	5 (19.23)	4 (6.90)	18 (17.65)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 7. Turnover (Small Firms)

Sl. No.	Monthly Turnover (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 15	6 (33.33)	12 (46.15)	19 (32.76)	37 (36.27)	Calculated Value CV	2.8535
2.	15 - 50	7 (38.89)	8 (30.77)	27 (46.55)	42 (41.18)	Table Value TV at 5 %	9.49
3.	50 and above	5 (27.78)	6 (23.08)	12 (20.69)	23 (22.55)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Results and Interpretation

(1) Relationships in Small Firms

✎ **Null Hypothesis :** As indicated by the Table 2, there is no relationship between capital structure (private sector or public sector) and the level of the quality system, and hence, the null hypothesis is accepted.

✎ **Hypothesis and Interpretation :** There is no relationship between capital investment and the level of the quality system .This hypothesis is rejected as we can conclude (from the Table 3) that there exists a relationship between capital investment and the level of the quality system in small firms.

✎ **Hypothesis and Interpretation :** The percentage of expenditure on quality control and the level of the quality system are two independent attributes. From the Table 4, it can be concluded that there exists a relationship between the percentage of expenditure on quality control and the level of the quality system in small firms.

Table 8. Personnel Cost Incurred (Small Firms)

Sl. No.	Personnel Cost Incurred/ Monthly (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 0.2	5 (27.78)	8 (30.77)	16 (27.59)	29 (28.43)	Calculated Value CV	1.3189
2.	0.2 to 1.0	9 (50.00)	12 (46.15)	34 (58.62)	55 (53.92)	Table Value TV at 5 %	9.49
3.	1.0 and above	4 (22.22)	6 (23.08)	8 (13.79)	18 (17.65)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 9. ISO Certification (Small Firms)

Sl. No.	Certified by ISO	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Certified	6 (33.33)	8 (30.77)	4 (6.89)	18 (17.65)	Calculated Value CV	1.3189
2.	Not Certified	12 (66.67)	18 (69.23)	54 (93.11)	84 (82.35)	Table Value TV at 5 %	9.49
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)	Degrees of Freedom	4

Table 10. Area of Selling (Small Firms)

Sl. No.	Area of Selling	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Within State	7 (38.89)	13 (50.00)	34 (58.62)	54 (52.94)	Calculated Value CV	7.5394
2.	Within India	6 (33.33)	8 (30.77)	22 (37.93)	36 (35.29)	Table Value TV at 5 %	9.49
3.	International	5 (27.78)	5 (19.23)	2 (3.45)	12 (11.76)	Degrees of Freedom	4
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

Table 11. Vendor Evaluation (Small Firms)

Sl. No.	Vendor Evaluation	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Quality	5 (27.78)	8 (30.77)	23 (39.66)	36 (35.29)	Calculated Value CV	13.2781
2.	Cost	4 (22.22)	6 (23.08)	8 (13.79)	18 (17.65)	Table Value TV at 5 %	11.070
3.	Popularity	6 (33.33)	5 (19.23)	14 (24.14)	25 (24.51)	Degrees of Freedom	4
4.	Delivery Time	3 (16.67)	7 (26.92)	13 (22.41)	23 (22.55)		
	Total	18 (100.00)	26 (100.00)	58 (100.00)	102 (100.00)		

✍ **Hypothesis and Interpretation :** There exists no relationship between the operating expenditure and the level of the quality system in small firms. As per the Table 5, this hypothesis stands accepted.

✍ **Hypothesis and Interpretation :** The percentage of operating expenditure on quality control / assurance and the level of the quality system are independent. As per the Table 6, there exists a relationship between the percentage of operating expenditure on quality control / assurance and the level of the quality system in small firms. Hence, the hypothesis is rejected.

✍ **Hypothesis and Interpretation :** There is no relationship between turnover and the level of the quality system in small firms. This hypothesis is accepted as the Table 7 indicates that there exists no relationship between turnover and the level of the quality system in small firms.

✍ **Hypothesis and Interpretation :** Personnel cost incurred and the level of the quality system are two independent attributes. From the Table 8, it can be inferred that personnel cost incurred does not influence the level of the quality system in small firms. Hence, this hypothesis is accepted.

Table 12. Capital Structure (Medium and Large Firms)

Sl. No.	Capital Structure	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Private	18 (64.29)	12 (75.00)	3 (75.00)	33 (68.75)	Calculated Value CV	0.4546
2.	Public	10 (35.71)	4 (25.00)	1 (25.00)	15 (31.25)	Table Value TV at 5 %	5.991
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)	Degrees of Freedom	2

Table 13. Capital Investment (Medium and Large Firms)

Sl. No.	Capital Investment (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 30	1 (3.57)	2 (12.50)	1 (25.00)	4 (8.33)	Calculated Value CV	0.5555
2.	30 - 50	9 (32.14)	4 (25.00)	1 (25.00)	14 (29.17)	Table Value TV at 5 %	9.49
3.	50 and above	18 (64.29)	10 (62.50)	2 (50.00)	30 (62.50)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 14. Percentage of Investment on Quality Control (Medium and Large Firms)

Sl. No.	Percentage of Investment to Q.C. to Total Capital invested	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 5	4 (14.28)	2 (12.50)	1 (25.00)	7 (14.58)	Calculated Value CV	0.2269
2.	5 - 10	5 (17.85)	4 (25.00)	1 (25.00)	10 (20.84)	Table Value TV at 5 %	9.49
3.	10 and above	19 (67.86)	10 (62.50)	2 (50.00)	31 (64.58)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 15. Operating Expenditure (Medium and Large Firms)

Sl. No.	Operating Expenditure (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 5.0	2 (7.14)	3 (18.75)	1 (25.00)	6 (12.50)	Calculated Value CV	1.0481
2.	5.0 to 10.00	23 (82.14)	9 (56.25)	2 (50.00)	34 (70.83)	Table Value TV at 5 %	9.49
3.	Above 10.00	3 (10.71)	4 (25.00)	1 (25.00)	8 (16.67)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

✍ **Hypothesis and Interpretation :** There is no relationship between ISO certification and the level of the quality system in small firms. The Table 9 indicates that there exists a relationship between the ISO certification and the level of the quality system in small firms. Hence, this hypothesis is rejected.

✍ **Hypothesis and Interpretation :** The area of selling and the level of the quality system are two independent attributes. It can be inferred from the Table 10 that the level of the quality system is independent of the area of selling within a state, within India, and internationally as well - this may be due to the insignificant number of exporters in the sample. Hence, the hypothesis is accepted.

✍ **Hypothesis and Interpretation :** Vendor evaluation and the level of the quality system are two independent attributes. According to the Table 11, there exists a relationship between vendor evaluation and the level of the quality systems in small firms. Hence, this hypothesis is rejected.

(2) Relationship Between Attributes of Medium and Large Firms and the Level of the Quality System in These Firms : This section attempts to analyze the relationship between attributes of medium and large firms and their level of the quality system.

Table 16 : Percentage of Operating Expenditure on Quality Control / Assurance (Medium and Large Firms)

Sl. No.	Percentage of Operating Expenditure on Quality Control / Assurance	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 10	4 (14.29)	1 (6.25)	1 (25.00)	6 (12.50)	Calculated Value CV	10.7075
2.	10 - 15	14 (50.00)	9 (56.25)	1 (25.00)	24 (50.00)	Table Value TV at 5 %	9.49
3.	15 and above	10 (35.71)	6 (37.50)	2 (50.00)	18 (37.50)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 17. Turnover (Medium and Large Firms)

Sl. No.	Turnover PM (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 50	4 (14.29)	1 (6.25)	1 (25.00)	6 (12.50)	Calculated Value CV	0.3429
2.	50 - 100	7 (25.00)	5 (37.50)	1 (25.00)	13 (27.08)	Table Value TV at 5 %	9.49
3.	100 and above	17 (60.71)	10 (62.50)	2 (50.00)	29 (60.42)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 18. Personnel Cost Incurred (Medium and Large Firms)

Sl. No.	Personal Cost Incurred (₹ Million)	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Below 0.1	2 (7.14)	2 (12.50)	1 (25.00)	5 (10.42)	Calculated Value CV	12.3872
2.	0.1 - 0.2	7 (25.00)	5 (31.25)	2 (50.00)	14 (29.17)	Table Value TV at 5 %	9.49
3.	0.2 and above	17 (67.86)	9 (56.25)	1 (25.00)	29 (60.42)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 19. ISO Certification (Medium and Large Firms)

Sl. No.	Certified by ISO	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Certified	18 (64.28)	10 (62.50)	2 (50.00)	30 (62.50)	Calculated Value CV	0.4242
2.	Not Certified	10 (35.72)	6 (37.50)	2 (50.00)	18 (37.50)	Table Value TV at 5 %	5.991
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)	Degrees of Freedom	2

✍ **Hypothesis and Interpretation :** There is no relationship between types of firms and the level of the quality system in these firms. This hypothesis is accepted as it is clear from the Table 12 that the level of a quality system is independent of the types of firms.

✍ **Hypothesis and Interpretation :** There is no relationship between capital investments and the level of the quality system in medium and large firms. As per the Table 13, the level of the quality system is independent of the capital investments and there exists no relationship between capital investments and the level of the quality system in the medium and large firms. Hence, the hypothesis is accepted.

✍ **Hypothesis and Interpretation :** Percentage of quality control expenditure on total capital investments and the level of the quality system are two independent attributes. The Table 14 indicates that there exists no relationship between the percentage of expenditure on quality control to the total capital investments and the level of the quality system in medium and large firms. Hence, the hypothesis is accepted.

✍ **Hypothesis and Interpretation :** The operating expenditure and the level of the quality system are independent with respect to each other. It can be inferred from the Table 15 that the level of the quality system is independent of the operating expenditure of the firms. Hence, the hypothesis is accepted.

Table 20. Area of Selling (Medium and Large Firms)

Sl. No.	Area of Selling	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Within State	4 (14.29)	2 (12.50)	1 (25.00)	7 (14.58)	Calculated Value CV	0.6333
2.	Within India	21 (75.00)	12 (75.00)	2 (50.00)	35 (72.92)	Table Value TV at 5 %	9.49
3.	International	3 (10.71)	2 (12.50)	1 (25.00)	6 (12.50)	Degrees of Freedom	4
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 21. Vendor Evaluation (Medium and Large Firms)

Sl. No.	Vendor Evaluation	Level of Quality System			Total	Chi-Square Test	
		High	Medium	Low			
1.	Quality	5 (17.86)	6 (37.50)	1 (25.00)	12 (25.00)	Calculated Value CV	14.5583
2.	Cost	5 (17.86)	2 (12.50)	1 (25.00)	8 (16.67)	Table Value TV at 5 %	11.070
3.	Popularity	9 (32.14)	2 (12.50)	1 (25.00)	12 (25.00)	Degrees of Freedom	6
4.	Delivery Time	9 (32.14)	6 (37.50)	1 (25.00)	16 (33.33)		
	Total	28 (100.00)	16 (100.00)	4 (100.00)	48 (100.00)		

Table 22. Comparison of Significant Factors w.r.t the Level of Quality System in Small, Medium, and Large Firms

Sl.No.	Factors with Level of Quality System	Small	Medium & Large
1.	Types of firms	Not significant	Not Significant
2.	Capital investment	Significant*	Not Significant
3.	Percentage expenditure (investment) on QC	Significant*	Not Significant
4.	Operating Expenditure	Not Significant	Not Significant
5.	Percentage operating expenditure on Quality Control / Assurance	Significant*	Significant*
6.	Turn-over	Not significant	Not Significant
7.	Personnel cost incurred	Not significant	Significant*
8.	ISO Certification	Significant*	Not Significant
9.	Area of selling	Not significant	Not Significant
10.	Vendor Evaluation	Significant*	Significant*

* Chi-Square for the given degree of freedom is at 5% level of significance

✍ **Hypothesis and Interpretation :** The percentage of operating expenditure on quality control / assurance and the level of the quality system are independent attributes. As per the Table 16, there exists a relationship between the percentage of operating expenditure on quality control / assurance and the level of the quality system in medium and large firms. Hence, the hypothesis is rejected.

✍ **Hypothesis and Interpretation :** There is no relationship between the turnover and the level of the quality system in small and medium firms. As per the Table 17, there exists no relationship between the turnover of the firms and the level of the quality system. Hence, the hypothesis is accepted.

✍ **Hypothesis and Interpretation :** There is no relationship between the personnel cost incurred and the level of the quality system. We can conclude from the Table 18 that the level of the quality system is dependent upon the personnel cost incurred in medium and large firms. Hence, the hypothesis is rejected.

✍ **Hypothesis and Interpretation :** ISO certification and the level of the quality system are independent attributes. From the Table 19, it can be inferred that there exists no relationship between the ISO certification and the level of the quality system in medium and large firms. This may be due to the fact the medium and large companies possess international regulatory approvals and hence, will have better quality systems than ISO certifications. Hence, the hypothesis is accepted.

⇒ **Hypothesis and Interpretation :** The area of selling and the level of the quality system are two independent attributes. The Table 20 indicates that the level of the quality system is independent of the area of selling. Hence, there exists no relationship between the area of selling and the level of the quality system in medium and large firms. This may be due to the fact that the sample contained minimum number of companies exporting to regulated markets like U.S.A and Europe. Hence, the hypothesis is accepted.

⇒ **Hypothesis and Interpretation :** There is no relationship between vendor evaluation and the level of the quality system. On the basis of the Table 21, we can conclude that the level of the quality system is dependent upon vendor evaluation. Hence, the hypothesis is rejected.

□

Summary and Conclusion

⇒ **Comparison Between Small, Medium, and Large Firms :** The factors influencing the level of the quality system (management) for small, medium, and large firms are depicted in the Table 22. It is inferred from the Table 22 that out of the selected ten variables, only five variables, namely capital investment, percentage investment on quality control, percentage operating expenditure on quality control / assurance, ISO certification, and vendor evaluation influenced the level of the quality system in the case of small firms producing pharmaceutical products. In case of medium and large firms, only three variables namely, percentage operating expenditure on quality control / assurance, personnel cost, and vendor evaluations influenced the level of the quality system in the study area. Percentage operating expenditure on quality control / assurance and vendor evaluations impact and influence the level of the quality system in all firms, irrespective of the size of the firm, that is, small, medium, or large firm in the study area. The inferences are based on the chi-square test, which is a robust non-parametric test used for impact evaluation and generating additional hypotheses. The results of the present study show that percentage operating expenditure on quality control and vendor evaluation emerged as two significant drivers of quality systems in the context of the pharmaceutical industry. The reason for vendor evaluation being a key driver of quality systems may be due to the fact that a large number of processes in the pharma industry are being outsourced.

□

Managerial Implications

Healthcare quality practices and regulations are critical factors that influence healthcare marketing strategies. With the recent Patient Protection and Affordable Care Act, the healthcare sector in the U.S. will be significantly transformed, bringing with it several legal and regulatory challenges that are worthy of research and introspection. The pharmaceutical industry in the U.S. has also considered legal and regulatory issues as among the most critical factors influencing its evolution and strategic growth. Yet, the attention given to these issues in the healthcare marketing and management literature has been scarce.

Similarly, in Tamil Nadu, in order to improve the level of quality control among pharmaceutical companies, the policy makers can implement changes in the regulations in vendor evaluations followed by raising the minimum percentage operating expenditure on quality control/assurance. Such kinds of measures would improve the level of quality control, irrespective of the size of the firms. If some targeted measures have to be taken in the small firms' category, the policy makers can focus on tweaking the regulations on capital investment, percentage investment on QC, and ISO certification. For improving the quality level among medium and large firms, regulators can modify the requirements on personnel cost incurred by the firms. This research is a small contribution in this direction. Since this study was restricted to Tamil Nadu, it needs to be emphasized that this study is not necessarily representative of the pharmaceutical industry in the country. For a generalized conclusion, a study is required to be carried out on a larger and on a pan India basis.

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