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Influence and Implementation of Quality Management System in Medical Device Industry

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Abstract: - **Aim**: The study aims to show the influence of the Quality Management System (QMS) in the medical device industry. Effective Quality Management System implementation is the principle factor for the manufacturer or manufacturing industries to improve the product and service Quality. In that case, this research study explores and finds out whether QMS helps in providing a competitive advantage to improve productivity or not? This paper gives an idea of how to implement QMS effectively.

Methods: A qualitative, descriptive study design was used. In this study, the statistical techniques for the analysis of the data gathered viz., Descriptive analysis and Inferential statistics.

Discussion: A strong statistical tool for examining the relationship between two or more variables of interest is regression analysis. In our study, we analyzed the impact of a quality management system (continuous quality improvement, policy and implementation, role of quality department, training, quality data reporting, QMS need, communication, customer focus) on overall performance using multiple regression analysis by Enter method.

Keywords: QMS, Quality management system , Competitive advantage , Medical device industry and Medical device manufacturing

1. INTRODUCTION

Quality Management Systems should address an organization's unique needs and customer requirements. If it comes to medical device quality management system, should address unique needs, customer requirements and regulatory requirements. Each element of a Quality Management System helps to achieve and satisfy the overall goals of the customers' and the manufacturer's expectations. The manufacturer or manufacturing industry's essential need is to maintain the effectiveness of QMS in accordance with the requirements of specific ISO standards and other applicable regulatory requirements depends upon the industry. The identification of the applicable QMS standards is a challenging phase in implementing the QMS, since this gives a shape to the product and its production. While implementing QMS, Organization should consider customer focus, evidence-based decision making as a prime factor. Quality is a crucial element that differentiates a company from its competitors. QMS is a tool to improve quality. By implementing proper quality management systems, it ensures that all necessary changes in your processes are implemented, which eventually leads to superior quality products and, in the end, bigger profits without micro monitoring by management.

OBJECTIVES OF THE STUDY

- To understand the implementation role in Quality management system effectiveness
- To understand the role of the Quality department, training to the employees and quality data reporting allows problems to be solved in the Quality management system
- To understand communication, customer focus and challenges in implementation and employee involvement role in the Quality management system
- To understand Quality indicator's importance in Quality management system implementation.

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LIMITATIONS OF THE STUDY

- The study is limited to only medical device manufacturing and distribution companies
- The sample size is limited to 568 and that may be a bias of the study
- The study period is around 3 months and a deep analysis about the research cannot be made.
- Respondent may fail to express their opinions and beliefs.

Descriptive study

The present study attempts to assess the Quality Management System in both general and IVD medical device manufacturing. It tries to give an idea about implementing QMS effectively and helps to find whether QMS helps in providing competitive advantage to improve productivity or not. Hence it is a descriptive analytical study.

Sources of data

Depending upon the sources of information available data can be classified as,

- Primary data
- Secondary data

Primary data

Primary data is a fresh data collected for the first time by the researcher. It was collected by administering standard communicable questionnaire from the employees and manager.

Secondary data

It refers to the already existing data. The study uses Government publications, websites, books, journal articles, internal records etc to collect the required data.

Data collection Procedure used in the research

Questionnaire

Questionnaire is used to collect the data for the study. One common questionnaire formulated

to collect the data respectively from middle management and executive level management.

Types of sampling used for the study: Random sampling

Sample size

Using random sampling method 568 respondents were selected from operational level employees and 80 were selected from executive level management of the medical device manufacturing companies.

2. ANALYSIS AND INTERPRETATION

Type of company employees	Frequency	Percent
General medical device	490	79.4
IVD medical device	127	20.6
Total	617	100

Table 1: Frequency distribution of types of company employees

From the above table, 79.4% sample or population in totality are using general medical device, whereas 20.4% are using IVD medical device. Maximum number of the population in totality is using general medical device and minimum number of the population in totality is using IVD medical device.

Year of establishment of companies	Frequency	Percent
Before 1990	149	24.1
1990-2000	160	25.9

2000-2010	245	39.7
After 2010	63	10.2
Total	617	100

Table 2: Frequency distribution of year of establishment of companies

From the above table and bar diagram, 24.1% of the companies were established before 1990, 25.9% of the company were established between the year 1990-2000, maximum number of the companies were established (39.7%) between the year 2000 and 2010 and the minimum number of the companies were established (10.2%) after year 2010. The highest number of companies were established between the year 2000 to 2010.

Year at company adopt QMS philosophy	Frequency	Percent
Before 1990	122	19.8
1990-2000	159	25.8
2000-2010	261	42.3
After 2010	75	12.2
Total	617	100

Table 3: Frequency distributions of year at company adopt QMS philosophy

From the above table, 19.8% of the companies under this study (both general medical device and IVD medical device) have adopted QMS philosophy before the year 1990. 25.8% of the company have adopted QMS philosophy between the years 1990-2000. Maximum number of the companies has adopted QMS philosophy (42.3%) between the year 2000 and 2010 and the minimum number of the companies has adopted QMS philosophy (12.2%) after the year 2010.

Continuous quality improvement

Continuous quality improvement	Mean	SD
Extent to which the top business continuously improves quality performance	3.63	0.49
PDCA (Plan do Check Act) used as tool for quality improvement	3.69	0.48
Continuous quality management sheet used for quality improvement	3.62	0.51
All employees agree quality and quality commitments	3.76	0.45

Table 4: Descriptive statistics of continuous quality improvement of company employees

From the above table the data for continuous quality improvement shows the average extent to which the top business continuously improves quality performance was 3.63 with a standard deviation of 0.49. Additionally, Plan do Check Act (PDCA) used as a tool for quality improvement was 3.69 with a standard deviation of 0.48. Mean of All employees agree quality and quality commitments was 3.76 with a standard deviation of 0.45. Based on the mean score PDCA used as tool for quality improvement (3.69) was the most important factor for continuous quality improvement and Continuous quality management sheet used for quality improvement (3.62) was the least important factor for continuous quality improvement.

Policy and implementation

Policy and implementation	Mean	SD
Organization's mission, vision, values, policy and targets are communicated to all the employees	4.35	0.63
Organization's quality vision is the basis for strategic planning and decisions throughout the organization.	4.13	0.76
Organization's strategy for quality is based on solid scientific information about customers' needs and satisfaction	4.38	0.72
Quality is an important KPI of all employees	4.23	0.67
Quality results are benchmarked against the best in the industry	4.27	0.71
Quality policy/ manual/ procedures are maintained as per Quality Management Systems.	4.22	0.71

Table 5: Descriptive statistics of policy and implementation

From the above table the data for policy and implementation, the average Organization's mission, vision, values, policy and targets are communicated to all the employees was 4.35 with a standard deviation of 0.63. Followed by Organization's quality vision is the basis for strategic planning and decisions throughout the organization with a mean 4.13 and a standard deviation of 0.76. Then the average of Organization's strategy for quality is based on solid scientific information about customers' needs and satisfaction was 4.38 with a standard deviation of 0.72. After that the average of Quality is an important KPI of all employees was 4.23 with a standard deviation of 0.67. Then the average of Quality results are benchmarked against the best in the industry was 4.27 with a standard deviation of 0.71. Additionally, the average of Quality policy/ manual/ procedures are maintained as per Quality Management Systems was 4.22 with a standard deviation of 0.71.

Based on the mean score Organization's strategy for quality is based on solid scientific information about customers' needs and satisfaction (4.38) was the most important factor for policy and implementation and Quality policy/ manual/ procedures are maintained as per Quality Management Systems. (4.22) was the least important factor for policy and implementation.

Role of the quality department

Role of the quality department	Mean	SD
Visibility of quality department.	4.36	0.68
Quality department's access to organizational top management	4.23	0.76
Responsibilities of quality department	4.40	0.68
Amount of co-ordination between the quality department and other departments	4.30	0.68
Coordinating various activities towards improving quality	4.18	0.73

Table 6: Descriptive statistics of role of the quality department

From the above table the data for role of the quality department, the average Visibility of quality department was 4.36 with a standard deviation of 0.68. Followed by Quality department's access to organizational top management with a mean 4.23 and a standard deviation of 0.76. Then the average of Responsibilities of quality department was 4.40 with a standard deviation of 0.68. After that the average of Amount of co-ordination between the quality department and other departments was 4.18 with a standard deviation of 0.73.

Based on the mean score Responsibilities of quality department (4.40) was the most important factor for Organization's role of the quality department and Quality department's access to organizational top management (4.23) was the least important factor for Responsibilities of quality department.

Training

Training	Mean	SD
Quality-related training given to hourly employees throughout the organization.	4.24	0.69
Quality-related training given to managers and supervisors throughout the division.	4.17	0.77
Training in “total quality concept" throughout the organization.	4.40	0.66
Training in basic statistical techniques in the organization as a whole.	4.27	0.69
Training in advanced statistical techniques in the organization as a whole.	4.19	0.72
Commitment of the organizational top management to employee training.	4.17	0.74
Availability of resources for employee training in the organization.	4.22	0.69
Aiming at training of all the personnel in the organization	4.27	0.71

Table 7: Descriptive statistics of training

From the above table the data for Training, the average Quality-related training given to hourly employees throughout the organization was 4.24 with a standard deviation of 0.69. Followed by Quality-related training given to managers and supervisors throughout the division with a mean 4.17 and a standard deviation of 0.77. Then the average of Training in “total quality concept" throughout the organization was 4.40 with a standard deviation of 0.66.

After that the average of Training in basic statistical techniques in the organization as a whole was 4.27 with a standard deviation of 0.69. Then the average of Training in advanced statistical techniques in the organization as a whole was 4.19 with a standard deviation of 0.72.

Followed by the average of Commitment of the organizational top management to employee training was 4.17 with a standard deviation of 0.74. After that, the average of Availability of resources for employee training in the organization was 4.22 with a standard deviation of 0.69.

Additionally, the average of Aiming at training of all the personnel in the organization was 4.27 with a standard deviation of 0.71.

Based on the mean score Training in “total quality concept" throughout the organization (4.40) was the most important factor for training, while Quality-related training given to managers and supervisors throughout the division (4.17), and Commitment of the organizational top management to employee training (4.17) both were the least important factors for training.

Quality data and reporting

Quality data and reporting	Mean	SD
Availability of quality data in the organization	4.29	0.69
Timeliness of quality data.	4.14	0.77
Extent to which quality data are available to managers and supervisors.	4.43	0.67
Extent to which quality data are used to evaluate supervisorial and managerial performance.	4.28	0.69
Extent to which quality data are displayed at employee work stations.	4.18	0.74
Publication/preparation of booklets, articles, video films and other quality training aids, etc.	4.12	0.67

Table 8: Descriptive statistics of quality data and reporting

From the above table the data for quality data and reporting, the average Availability of quality data in the organization was 4.29 with a standard deviation of 0.69. Followed by the Timeliness of quality data with a mean 4.14 and a standard deviation of 0.77. Then the average of Extent to which quality data are available to managers and supervisors was 4.43 with a standard deviation of 0.67. After that the average of Extent to which quality data are used to evaluate supervisorial and managerial performance was 4.28 with a standard deviation of 0.69. Followed by the Extent to which quality data are displayed at employee work stations was 4.18 with a standard deviation of 0.74. Additionally, the average of Publication/preparation of booklets, articles, video films and other quality training aids, etc. was 4.12 with a standard deviation of 0.67.

Based on the mean score Extent to which quality data are available to managers and supervisors (4.43) was the most important factor for quality data and reporting, while Publication/preparation of booklets, articles, video films and other quality training aids, etc. (4.12) was the least important factor for quality data and reporting.

QMS need

QMS Need	Mean	SD
QMS improves productivity	4.29	0.69
Quality impact in employee mind	4.20	0.76
SOP creation reduces communication error and workflow improvement	4.40	0.66
Improvement in company growth	4.27	0.68
Evidence based decision making	4.16	0.74

Table 9: Descriptive statistics of QMS need

From the above table the data for QMS Need, the average of the QMS improves productivity was 4.29 with a standard deviation of 0.69. Followed by the Quality impact in employee mind was 4.20 and a standard deviation of 0.76. Then the average of the SOP creation reduces communication error and workflow improvement was 4.40 with a standard deviation of 0.66. After that the average of the Improvement in company growth was 4.27 with a standard deviation of 0.68. Additionally, the average of Evidence based decision making was 4.16 with a standard deviation of 0.74.

Based on the mean score SOP creation reduces communication error and workflow improvement (4.40) was the most important factor for QMS need, while Evidence based decision making (4.16) was the least important factor for QMS need in the general medical device and IVD medical device companies.

Communication

Communication	Mean	SD
SOP procedure confirms current practice	4.26	0.67
Communication procedure is effective	4.15	0.78
SOP creation reduces communication error and improves process flow	4.37	0.71
SOP is easy to understand, agreeable and easy to follow	4.22	0.70
Communication based meeting / Training will conduct by QA	4.17	0.74

Table 10: Descriptive statistics of communication

From the above table the data for communications, the average of the SOP procedure confirms current practice was 4.26 with a standard deviation of 0.67. Followed by the Communication procedure is effective was 4.15 and a standard deviation of 0.78. Then the average of the SOP creation reduces communication error and improves process flow was 4.37 with a standard deviation of 0.71. After that the average of the SOP is easy to understand, agreeable and easy to follow was 4.22 with a standard deviation of 0.70. Additionally, the average of Communication based meeting / Training will conduct by QA was 4.17 with a standard deviation of 0.74.

Based on the mean score, SOP creation reduces communication error and improves process flow (4.37) was the most important factor for communication, while Communication based meeting / Training will conduct by QA (4.17) was the least important factor for communication in the general medical device and IVD medical device companies.

Customer focus

Customer focus	**Mean**	**SD**
Establishing valid customer requirements & expectations	4.32	0.66
Development and use of customer satisfaction measures	4.13	0.77
Creating partnerships with key customers	4.38	0.70
Linking customer requirements to the development of new products and services	4.28	0.66
Developing and communicating policies and procedures to remedy service errors	4.20	0.71
Empowering everyone in the organization to delight the customer	4.22	0.71
Gathering continuous feedback from customers	4.33	0.70
Anticipating customers' future needs	4.20	0.68
Offering QMS training to customers	4.25	0.74
Information provided to the customers/consumers through informative labeling, brochures and other product literature	4.29	0.67
Establishing and participating in joint improvement teams with customers	4.26	0.68
On-time delivery	4.28	0.67
Product availability	4.33	0.70
Accessibility of key staff	4.25	0.72
Follow up with the customers	4.28	0.69
Customer Satisfaction Index	4.31	0.68
Number and nature of customer complaints	4.07	0.81
Redressal mechanism including time of response and final redressal	4.23	0.67
Customer returns (by value and quantity)	4.22	0.65
Establishing valid customer requirements & expectations	4.37	0.69

Table 11: Descriptive statistics of customer focus

From the above table the data for customer focus, the average of the Establishing valid customer requirements & expectations was 4.32 with a standard deviation of 0.66. Followed by the mean of Development and use of customer satisfaction measures was 4.13 and a standard deviation of 0.77. Then the average of the Creating partnerships with key customers was 4.37 with a standard deviation of 0.70. After that the average of Linking customer requirements to the development of new products and services was 4.28 with a standard deviation of 0.66. Then the average of Developing and communicating policies and procedures to remedy service errors was 4.20 with a standard deviation of 0.71.

Followed by the average of Empowering everyone in the organization to delight the customer was 4.22 with a standard deviation of 0.71. After that, the average of Gathering continuous feedback from customers was 4.33 with a standard deviation of 0.70. Then the average of Anticipating customers' future needs was 4.20 with a standard deviation of 0.68. Followed by the average of Offering QMS training to customers was 4.25 with a standard deviation of 0.74.

After that, the average of Information provided to the customers/consumers through informative labeling, brochures and other product literature was 4.29 with a standard deviation of 0.67. Then the average of Establishing and participating in joint improvement teams with customers was 4.26 with a standard deviation of 0.68. Followed by the average of On-time delivery was 4.28 with a standard deviation of 0.67. After that, the average of Product availability was 4.33 with a standard deviation of 0.70. Then the average of Accessibility of key staff was 4.25 with a standard deviation of 0.72. Followed by the average of Follow up with the customers was 4.28 with a standard deviation of 0.69. After that, the average of Customer Satisfaction Index was 4.31 with a standard deviation of 0.68. Then the average of Number and nature of customer complaints was 4.07 with a standard deviation of 0.81. Followed by the average of Redressal mechanism including time of response and final redressal was 4.23 with a standard deviation of 0.67. After that, the average of Customer returns (by value and quantity) was 4.22 with a standard deviation of 0.65. Additionally, the average of Establishing valid customer requirements & expectations was 4.37 with a standard deviation of 0.69.

Based on the mean score, creating partnerships with key customers (4.38) was the most important factor for customer focus, while Number and nature of customer complaints (4.07) was the least important factor for customer focus.

Chi-square test for association between level of quality management system and level of performance

Level of quality management system	**Level of performance**			**Total**	**Chi-square value**	**P value**
	Low	Moderate	High			
Low	92 (56.4) [58.2]	50 (30.7) [17.5]	21 (12.9) [12.1]	163 (100.0) [26.4]	289.642	<0.001**
Moderate	46 (15.5) [29.1]	209 (70.4) [73.1]	42 (14.1) [24.3]	297 (100.0) [48.1]		
High	20 (12.7) [12.7]	27 (17.2) [9.4]	110 (70.1) [63.6]	157 (100.0) [25.4]		
Total	158 (25.6) [100.0]	286 (46.4) [100.0]	173 (28.0) [100.0]	617 (100.0) [100.0]		

Table 12: Chi-square test for association between level of quality management system and level of performance

** denotes significant at 1% level

Since P value is less than 0.01, the null hypothesis is rejected at 1 percent level of significance. Hence the table concluded that there is strong association between level of quality management system and level of performance. Based on the row percentage, Level of quality management system (Low), 56.4% companies are low Level of performance, 30.7% are moderate Level of performance and 12.9% are high Level of performance. The, Level of quality management system (Moderate), 15.5% companies are low Level of performance, 70.4% are moderate Level of performance and 14.1% are high Level of performance. The, Level of quality management system (High), 12.7% companies are low Level of performance, 17.2% are moderate Level of performance and 70.1% are high Level of performance. Hence, The Level of quality management system (Low) are low level on performance and in Level of quality management system (High) are high level on performance.

Factors of quality management system, global competitiveness and performance	Number of managers				F value	P value
	Up to 10	11-100	101-750	Above 750		
Continuous quality Improvement	14.55[a] (.98)	14.53[a] (.98)	14.83[b] (.82)	14.79[b] (.76)	4.635	0.003**
Policy and implementation	25.75[b] (1.57)	24.82[a] (1.32)	25.58[b] (1.53)	25.82[b] (1.64)	9.792	<0.001**
Role of quality department	21.38[b] (1.68)	21.01[a] (1.23)	21.54[b] (1.52)	21.69[b] (1.41)	4.661	0.003**
Training	33.75[b] (2.16)	33.06[a] (1.79)	33.70[b] (2.20)	34.73[c] (2.07)	15.517	<0.001**
Quality data reporting	25.19[ab] (2.15)	24.93[a] (1.50)	25.52[bc] (1.47)	25.83[c] (1.67)	7.124	<0.001**
QMS need	21.12[a] (1.48)	20.85[a] (1.32)	21.46[b] (1.35)	21.61[b] (1.35)	8.097	<0.001**
Communication	20.98[ab] (1.53)	20.65[a] (1.35)	21.15[b] (1.34)	21.58[c] (1.47)	10.130	<0.001**
Customer focus	84.91[b] (5.30)	82.84[a] (3.40)	84.82[b] (3.85)	87.01[c] (5.01)	18.861	<0.001**

Table 13: ANOVA for significant difference among number of managers with respect to factors of the quality management system, global competitiveness, and performance

Note:

1. The value within the bracket refers to SD
2. ** denotes significant at 1% level.
3. Different alphabet among Educational Qualifications denotes significant at 5% level using Duncan Multiple Range Test (DMRT)

Since P value is less than 0.01, null hypothesis is rejected at 1% level with regard to the Factors of Continuous quality improvement, Policy and implementation, Role of quality department, Training, Quality data reporting, QMS need, Communication, Customer focus. Hence there is significance among number of managers with respect to factors of quality management system, global competitiveness and performance with regard to the Factors Continuous quality improvement, Policy and implementation, Role of quality department, Training, Quality data reporting, QMS need, Communication, Customer focus.

There are no other factors has to influence among a number of managers with respect to factors of quality management system, global competitiveness and performance, since no other P value is greater than 0.05. Hence the null hypothesis is rejected at 5% level with regard to Overall quality management system, Overall global competitiveness and Overall performance.

Is there a best option in Quality Management System implementation?

The difference between a cultural and a process perspective in these continuous improvement strategies are discussed below;

Quality versus productivity:

The decision to embark on either a quality improvement programme or a productivity improvement programme is not a straightforward one. It is clear that for any organization to be successful it must be actively improving both quality and productivity, and so elements of both need to be included in their quality indicators in quality

management system. Perhaps It is the focus of the strategies that will be a better starting point for deciding on the best strategy.

Cultural versus process focus:

The difference in the focus of a strategy may be the most significant factor in deciding which strategy to employ. A strategy with a cultural focus will require a more empowering form of leadership and an ability and willingness to distribute knowledge. A strategy that has a process focus will generally be easier with a more directive form of leadership, in that this approach has to communicate and initiate new procedures and processes, and to ensure that these are implemented effectively. The result will be more centralized knowledge that requires staff to be trained so that they are competent in the methods that are to be used.

Continuous review of Quality Management System:

Periodic review need to be initiated to identify suitability of Quality Management System by quality team. Experts involvement in reviewing suitability of quality management system will play major role to identify the gaps. Quality review always should focus on safety and efficacy of the device to formulate the strategy.

Training to all level employees:

Training is the common tool to achieve Quality Management System effectiveness. But continuous training in all level management will play big impact. Usually many common problems in QMS due to employee change in organization.Any training in Quality Management System needs training effectiveness to confirm the employee understanding the concept about the training.

CONCLUSION:

The results of the study would contributed exactly to understanding the Quality Management System in Medical Devices industry. Especially who already implemented quality management system to improve their quality journey. It will be also great benefit those focus on quality work in the medical device industry. In general, the results in this study contributed to the following;

1. The survey questionnaire and google questionnaire could be used in future study
2. Organaisation intended to improve Quality management system should focus in quality techniques, periodic review of Quality Management System and continuous training.
3. Firms intended to install Quality Management System should proceed to establish process control
4. Expert involvement in process control improves Quality Management System effectiveness.

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