CONTRIBUTION OF IMPLEMENTATION METHOD AND TRAINING WITH THE REFERENCE TO MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM IN CHENNAI

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ABSTRACT

ISO 13485:2016 is commonly used Quality Management system in Medical Device Industry. Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. QMS usually complies with Structure, Responsibilities, Procedures, Processes and Resources. Quality should be built into the product, and testing alone cannot be relied on to ensure product quality in the Medical Device QMS. Quality Management system that involves Continual Improvement. Uses strategy, data, and communications to integrate the quality discipline into the culture and activities of the organization. The main objective of the study is to know about the Contribution of implementation method and Training in the Medical device manufacturing companies and to analyse the level of acceptance of QMS in their manufacturing companies. It is important to understand Implementation method and Training to ensure Quality improvement culture on process and Quality Indicators. For this purpose a sample of 90 was collected with employees and 30 was collected with top level management were percentage analysis, Anova, multiple regression and t-test were used as tools to analyse the data. The conclusion is that when compared with other dimensions on survey, Implementation method and Training has the highest impact with demographic profiles and other factors related to QMS. Training Methods, Implementation tools, Process and Procedure alignment in Practice plays big role to implement proper Quality Management system. QMS has been implemented effectively in the Medical Device Manufacturing companies but Management Representative has to arrange continuous training in QMS to improve process based on customer and Regulatory requirement.

Key words *– QMS, Adoption and Quality system*

INTRODUCTION

Quality Management System is a part of TQM implementation which increases Productivity and improves Customer Satisfaction. To obtain good QMS implementation, organization need proper Standard Operating Procedure and implementation. There are many tools used in TQM, but QMS is worldwide recognised and accepted. Total quality management is one of the most popular and durable management concepts and it has passed through a number of phases since 1920,s. The RooDrucker, Juran, Deming, Ishikawa, Crosby, Feigenbaum and countless other people have studied, practiced, and tried to refine the process of organizational managements of Total Quality Management (TQM)

A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. The Quality

Management system key elements are Management Responsibilities, Resources, Manufacturing Operations and Evaluation Activities. Quality system concept in Medical device QMS is mainly Quality by Design and Product Development, Quality Risk Management , CAPA (Corrective and Preventive Action), Change Control and The Quality Unit.

STATEMENT OF PROBLEM

- To suggest a framework for successful implementation of Quality management initiatives in Medical Device industry.
- To analyse the relationship between factors that influence implementation of Quality Management initiatives especially Contribution of Implementation method and Training.
- To measure the strength of the factors that influence implementation of Quality Management initiatives

DESCRIPTIVE STUDY

The present study attempts to assess the Quality Management System in the Medical Device manufacturing companies. It tries to assess the Contribution of Implementation method and Training in QMS of the organizations. Hence it is a descriptive study.

Sources of Data:

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

- Primary Data
- Secondary Data

Primary Data: The primary data are those, which are collected for the first time by the researcher. It is the fresh data. It was collected by administering questionnaire from the employees.

Secondary Data: It refers to the already existing data. This study uses the internet, books, published articles, journals, and Newspaper articles methods to collect the 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 90 respondents were selected from operational level employees and 30 were selected from Executive level management of the Medical Device manufacturing companies.

LIMITATIONS OF THE STUDY

- The study is limited to only Medical Device manufacturing companies.
- The sample size is limited to 90 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.

ANALSIS AND INTERPRETATION

Variables of the company	Particulars	Frequency	Percent
Type of Company	General Medical Device	21	23.3
	IVD Medical Device	41	45.6
	Both	19	21.1
	Other	9	10.0
	Total	90	100.0
Product Category	Domestic	12	13.3
	International	3	3.3
	Both	75	83.3
	Total	90	100.0
Year of company adopting QMS philosophy	Before 2010	38	42.2
	After 2010	52	57.8
	Total	90	100.0

Type of Company

Out of 90 respondents 23.3% are General Medical Device manufacturing companies, 45.6% are IVD Medical Devices, 21.1% are both (General Medical and IVD Medical companies) and 10.0% are other type of companies. 13.3% dealing with domestic product category, 3.3% dealing with International product category, and 83.3% are in both national and international category. 42.2% are adopted QMS before 2010 with their company and 57.8% have adopted after 2010.

CORRECT TOOLS OF QUALITY CONTROL

Factors	Particulars	Frequency	Percent
Engineering	Pareto Charts	6	6.7
	Cause & Effect Diagram	3	3.3
	Check Sheets	37	41.1
	Histograms	6	6.7
	Statistical Process Control	14	15.6
	Benchmarking	3	3.3
	Six Sigma	9	10
	Others	12	13.3
	Total	90	100
Manufacturing	Cause & Effect Diagram	6	6.7
	Stratification	3	3.3
	Check Sheets	12	13.3
	Histograms	14	15.6
	Scatter Diagrams	6	6.7
	Control Charts	18	20
	Statistical Process Control	9	10
	Benchmarking	13	14.4

	Six Sigma	9	10
	Total	90	100
Quality	Cause & Effect Diagram	21	23.3
	Check Sheets	9	10
	Histograms	15	16.7
	Scatter Diagrams	5	5.6
	Statistical Process Control	12	13.3
	Benchmarking	16	17.8
	Six Sigma	9	10
	Others	3	3.3
	Total	90	100
Research & Development	Check Sheets	9	10
	Histograms	5	5.6
	Scatter Diagrams	6	6.7
	Control Charts	3	3.3
	Statistical Process Control	30	33.3
	Benchmarking	16	17.8
	Six Sigma	6	6.7
	Others	15	16.7
	Total	90	100
Operations	Stratification	3	3.3
	Check Sheets	30	33.3
	Histograms	6	6.7
	Control Charts	3	3.3
	Statistical Process Control	21	23.3
	Benchmarking	3	3.3
	Six Sigma	12	13.3
	Others	12	13.3
	Total	90	100
Finance	Pareto Charts	9	10
	Stratification	3	3.3
	Check Sheets	6	6.7
	Histograms	11	12.2
	Control Charts	3	3.3
	Statistical Process Control	22	24.4
	Others	36	40
	Total	90	100

Out of 90 respondents 6.7% using Pareto Charts, 3.3% are using Cause & Effect Diagram, 41.1% are using Check Sheets, 6.7% using Histograms, 15.6% using Statistical Process Control, 3.3% are using Benchmarking, 10% using Six Sigma, and 13.3% using other tools with engineering companies. 3.3% using Stratification, 6.7% are using Cause & Effect Diagram, 13.3% are using Check Sheets, 15.6% using Histograms, 6.7% using Scatter

Diagrams, 20% are using Control Charts, 10% using Six Sigma, and 10% using Statistical Process Control,14.4% using Benchmarking with manufacturing companies. 3.3% using Stratification, 23.3% are using Cause & Effect Diagram, 10% are using Check Sheets, 16.7% using Histograms, 5.6% using Scatter Diagrams, 17.8% are using Benchmarking, 10% using Six Sigma, and 13.3% using Statistical Process Control as their Quality control tool. 10% using Check Sheets, 5.6% are using Histograms, 3.3% are using Control Charts, 16.7% using others, 6.7% using Scatter Diagrams, 17.8% are using Benchmarking, 10% using Six Sigma, and 33.3% using Statistical Process Control in Research & Development as their Quality control tool. 3.3% using Stratification, 33.3% using Check Sheets, 6.7% are using Histograms, 3.3% are using Control Charts, 13.3% using others, 3.3% are using Benchmarking, 13.3% using Six Sigma, and 23.3% using Statistical Process Control in Operations as their Quality control tool. 10% using Pareto Charts, 3.3% are using Stratification, 6.7% are using Check Sheets, 12.2% using Histograms, 24.4% using Statistical Process Control, 3.3% are using Control Charts, and 40% using other tools in finance based companies.

DESCRIPTIVE STATISTICS

ROLE OF THE QUALITY DEPARTMENT

	N	Mean	Std. Deviation
RQD1	90	3.73	.897
RQD2	90	3.98	.936
RQD3	90	4.17	.864
RQD4	90	3.91	.802
RQD5	90	4.08	.796

It depicts that there is a high visibility of quality department (3.73), quality department has high accessibility towards organizational top management (3.98), and also there is a high co-ordination between the quality department and other departments (3.91), respondents said that quality department is having very high responsibilities (4.17), and also there is a very high coordination in various activities towards improving quality (4.08).

TRAINING

	N	Mean	Std. Deviation
TR1	90	3.93	.969
TR2	90	3.70	1.106
TR3	90	3.83	.738
TR4	90	3.70	.867
TR5	90	3.43	.925
TR6	90	3.62	1.077
TR7	90	3.76	.769
TR8	90	3.86	1.012

`It depicts that there is a high level of Quality-related training given to hourly employees throughout the organization (3.93), Quality-related training given to managers and supervisors throughout the divisions are high (3.70), high training in “total quality concept" throughout the organization (3.83), Training in basic statistical techniques in the organization as a whole are high (3.70), there is a high level training in advanced statistical techniques

(3.43), high level of commitment towards employee training by top management (3.62), there is a high availability of resources for employee training in the organization (3.76), and also aiming is high at training of all the personnel in the organization (3.86).

QMS NEED

	N	Mean	Std. Deviation
QMS1	90	3.93	.731
QMS2	90	3.93	.969
QMS3	90	4.13	.674
QMS4	90	4.06	.740
QMS5	90	3.97	1.022

It shows that the QMS helps in improving high productivity (3.93), there is a high quality impact in employee mind (3.93), evidence based decision Making is high (3.97), and respondents said that creating SOP has a very high chance of reducing communication error and increasing work flow improvement (4.13), and also said that there is very high level of improvement in company growth (4.06).

CUSTOMER FOCUS

	N	Mean	Std. Deviation
CF1	90	3.84	.598
CF2	90	4.16	.778
CF3	90	3.99	.906
CF4	90	4.10	.984
CF5	90	4.06	.725
CF6	90	3.98	.734
CF7	90	4.06	.725
CF8	90	4.14	.815
CF9	90	3.52	1.019
CF10	90	3.73	1.036
CF11	90	4.04	.923
CF12	90	3.86	1.001
CF13	90	3.72	1.081
CF14	90	4.00	.687
CF15	90	3.94	.693
CF16	90	3.94	.812
CF17	90	3.92	.939
CF18	90	3.94	.725
CF19	90	3.74	1.137
CF20	90	3.83	.824

The above table shows that there is a high establishment of valid customer requirements & expectations (3.84), high chance of creating partnerships with key customers (3.99), high empowering of everyone in the organization to delight the customer (3.98), high offering of QMS training to customers (3.52), providing of information to the customers/consumers are high through informative labeling, brochures and other product literature (3.73), high chances of on-time delivery (3.86), high availability of products (3.72), following up of customers are high (3.94), there is a high customer satisfaction index(3.94), number and nature of customer complaints are high (3.92), high redressal mechanism including time of response and final redressal(3.94), customer returns are high (by value and quantity) (3.74), and also said that there is high warranty payments (3.83). respondents said that very high development and use of customer satisfaction measures (4.16), linking customer requirements to the development of new products and services are very high (4.10), developing and communicating policies and procedures to remedy service errors are very

high (4.06), very high gathering of continuous feedback from customers (4.06), very high anticipation of customers future needs (4.14), there is a very high establishment and participation in joint improvement teams with customers (4.04), and also there is a very high accessibility of key staff (4.00).

CHALLENGES IN IMPLEMENTATION

	N	Mean	Std. Deviation
CI1	90	3.93	.818
CI2	90	3.93	1.036
CI3	90	3.97	.917
CI4	90	3.89	.800
CI5	90	3.92	.890

It reveals that high consulting knowledge is needed to implement QMS (3.93), Employee acceptability are high (3.93), Management acceptability are high (3.97), high impact of local regulation and regulatory (3.89), and also said that Cost of implementations are high (3.92).

QUALITY IMPROVEMENT

	N	Mean	Std. Deviation
QI1	90	3.89	.608
QI2	90	3.82	.919
QI3	90	3.96	.886
QI4	90	4.20	.837

It depicts that there is a high improvement of Quality performance by QMS (3.89), Quality is a highly important concept to each person of the organization (3.82), QMS highly helping in reducing errors and improving Quality attributes (3.96), and respondents said that Quality performance monitoring procedure SOP is very highly agreeable and monitor able (4.20).

PROCESS MANAGEMENT / OPERATING PROCEDURES

	N	Mean	Std. Deviation
PMOR1	90	3.92	.877
PMOR2	90	3.82	.907
PMOR3	90	3.70	1.106
PMOR4	90	3.87	.927
PMOR5	90	3.96	.898
PMOR6	90	3.89	.841
PMOR7	90	3.86	.955
PMOR8	90	3.71	1.084
PMOR9	90	3.73	1.100
PMOR10	90	3.87	.927

It depicts that there is a high use of acceptance sampling for accepting/rejecting lots or batches of work (3.92), there is a high amount of preventive equipment maintenance (3.82), automation of inspection, review or checking of work are high to an extent (3.70), high amount of incoming inspection, review or checking (3.87), high Amount of in-process inspection, review or checking (3.96), amount of final inspection, review or checking are high (3.89), high stability of production scheduling/work distribution (3.86), high degree of automation in the process(3.71), process designing "fool-proof" and minimizing the chances

of employee errors are high to an extent (3.73), and also said that there is a high clarity of work or process instructions given to employees(3.87).

	N	Mean	Std. Deviation
CS1	90	3.86	.628
CS2	90	4.09	.788
CS3	90	3.96	.959
CS4	90	3.99	.966
CS5	90	4.04	.886
CS6	90	4.01	.966
CS7	90	4.04	.847
CS8	90	3.84	1.059
CS9	90	3.33	1.171
CS10	90	3.83	1.164
CS11	90	3.74	.978
CS12	90	3.81	.959
CS13	90	4.02	1.038
CS14	90	4.03	.800
CS15	90	3.77	.849
CS16	90	3.97	.800
CS17	90	3.79	1.076
CS18	90	3.91	.990
CS19	90	3.78	1.025
CS20	90	4.01	.906

The above table shows that there is a high establishing of valid customer requirements & expectations (3.86), Creating of partnerships with key customers are high (3.96), high linking of customer requirements to the development of new products and services (3.99), high anticipating of customers' future needs (3.84), there is a high Offering of QMS training to customers (3.33), providing of information to the customers/consumers are high through informative labeling, brochures and other product literature (3.83), Establishing and participating in joint improvement teams with customers are high (3.74), high chances of On-time delivery (3.81), following up of customers are high (3.77), there is a high Customer Satisfaction Index(3.97), number and nature of customer complaints are high (3.79), high redressal mechanism including time of response and final redressal(3.91), Customer returns are high (by value and quantity) (3.78), Linking customer requirements to the development of new products and services are high (3.99), and also said that there is very high warranty payments (4.01). respondents said that very high development and use of customer satisfaction measures (4.09), high availability of products (4.02), Developing and communicating policies and procedures to remedy service errors are very high (4.04), very high gathering of continuous feedback from customers (4.01), very high Anticipation of customers future needs (4.14), and also there is a very high accessibility of key staff (4.03).

KRUSKAL WALLIS TEST

COMPARISON BETWEEN YEAR OF COMPANY ADOPTING QMS PHILOSOPHY AND FACTORS RELATED TO QUALITY MANAGEMENT SYSTEM

Ho1: There is no relationship between year of company adopting QMS philosophy and factors related to Quality Management System.

Dimensions	Year of company adopting QMS philosophy	N	Mean Rank	Chi-square	Sig
Role of the Quality Department	Before 2010	38	46.18	.046	.831
	After 2010	52	45.00		
	Total	90			
Training	Before 2010	38	47.32	.320	.572
	After 2010	52	44.17		
	Total	90			
QMS Need	Before 2010	38	41.72	1.402	.000
	After 2010	52	48.26		
	Total	90			
Customer Focus	Before 2010	38	44.63	.073	.787
	After 2010	52	46.13		
	Total	90			
Challenges in Implementation	Before 2010	38	52.25	4.467	.035
	After 2010	52	40.57		
	Total	90			
Quality Improvement	Before 2010	38	43.14	.548	.459
	After 2010	52	47.22		
	Total	90			
Process Management / Operating Procedures	Before 2010	12	14.17	1.170	.000
	After 2010	14	12.93		
	Total	26			
Customer Satisfaction	Before 2010	38	49.64	1.661	.000
	After 2010	52	42.47		
	Total	90			

There is no relationship between year of company adopting QMS philosophy and Role of the Quality Department (0.831), Training (0.572), Customer Focus (0.787), and Quality Improvement (0.459).

There is a relationship between year of company adopting QMS philosophy and QMS Need (0.000), Challenges in Implementation (0.035), Process Management / Operating Procedures (0.000), Customer Satisfaction (0.000).

Comparison between type of company and factors related to Quality Management System

Ho1a: There is a significant between type of company and factors related to Quality Management System.

Dimensions	Type of company	N	Mean	Std. Deviation	F	Sig
Role of the Quality Department	General Medical Device	21	4.1714	.59426	1.275	.288
	IVD Medical Device	41	3.9317	.55608		
	Both	19	3.9579	.53574		
	Other	9	3.7333	.95394		
	Total	90	3.9733	.61165		
Training	General Medical Device	21	4.0200	.62575	33.175	.000
	IVD Medical Device	41	3.8105	.34668		
	Both	19	3.9237	.44196		
	Other	9	2.2933	.53254		
	Total	90	3.7316	.66825		
QMS Need	General Medical Device	21	4.0000	.52536	1.367	.258
	IVD Medical Device	41	4.0244	.46302		
	Both	19	4.1263	.56258		
	Other	9	3.6667	1.00000		
	Total	90	4.0044	.57199		
Customer Focus	General Medical Device	21	4.0286	.56315	2.877	.041
	IVD Medical Device	41	3.8110	.38786		
	Both	19	4.1711	.41141		
	Other	9	3.7000	1.00902		
	Total	90	3.9267	.53962		
Challenges in Implementation	General Medical Device	21	4.2000	.56921	3.928	.011
	IVD Medical Device	41	3.8146	.57687		
	Both	19	4.0947	.34233		
	Other	9	3.4667	1.17898		
	Total	90	3.9289	.64950		
Quality Improvement	General Medical Device	21	4.1786	.66682	1.896	.136
	IVD Medical Device	41	3.8171	.46779		
	Both	19	4.0395	.58490		
	Other	9	4.0000	.86603		
	Total	90	3.9667	.59751		
Process Management / Operating Procedures	General Medical Device	7	4.0714	.30394	1.011	.406
	IVD Medical Device	10	3.5300	1.04674		
	Both	6	3.7500	.53944		

	Other	3	4.2000	.60828		
	Total	26	3.8038	.75762		
Customer Satisfaction	General Medical Device	21	4.1786	.63336		
	IVD Medical Device	41	3.6744	.49017		
	Both	19	4.1658	.41098	5.879	.001
	Other	9	3.6333	.94108		
	Total	90	3.8917	.61307		

There is a significant between type of company and Role of the Quality Department (0.288), QMS Need (0.258), Quality Improvement (0.136), and Process Management / Operating Procedures (0.406).

There is no significant between type of company and Training (0.000), Customer Focus (0.041), Challenges in Implementation (0.011), and Customer Satisfaction (0.001).

FINDINGS

- Most of the respondents are IVD Medical Device companies.
- Majority of the respondents are dealing in both domestic and international product category.
- Maximum of the respondents adopted QMS philosophy after 2010.
- Most of the engineering companies are using Check Sheets as their Quality control tool.
- Maximum of the Manufacturing companies are using Control Charts as their Quality control tool.
- Most of the respondents are using Cause & Effect Diagram in quality as their Quality control tool.
- Maximum of the respondents are using Statistical Process Control in Research & Development as their Quality control tool.
- Most of the respondents are using Check Sheets in Operations as their Quality control tool.
- Maximum of the finance companies are using other tools as their Quality control tool.

Comparison between year of company adopting QMS philosophy and factors related to Quality Management System

QMS Need

It depicts that the companies adopting QMS philosophy after 2010 have higher level of acceptance towards QMS need.

Challenges in Implementation

It depicts that the companies adopting QMS philosophy Before 2010 have higher level of acceptance towards Challenges in Implementation**.**

Process Management / Operating Procedures

It depicts that the companies adopting QMS philosophy Before 2010 have higher level of acceptance towards Process Management / Operating Procedures.

Customer Satisfaction

It depicts that the companies adopting QMS philosophy Before 2010 have higher level of acceptance towards Customer Satisfaction.

Comparison between type of company and factors related to Quality Management System

Training

The respondents whose company are General Medical Device manufacturing (4.02) said there is very high training, who are in IVD Medical Device manufacturing (3.81), and Both (3.92) said there is high training, and Others (2.29) said that the training is low with reference to factors related to Quality Management System.

Customer Focus

The respondents whose company is General Medical Device manufacturing (4.02) and both (4.17) said there is very high customer focus, who are in IVD Medical Device manufacturing (3.81), and Others (3.70) said that customer focus is high with reference to factors related to Quality Management System.

Challenges in Implementation

The respondents whose company is General Medical Device manufacturing (4.20) and both (4.09) said they are facing very high challenges in Implementation, who are in IVD Medical Device manufacturing (3.81) and others (3.46) said that challenges are high in implementation with reference to factors related to Quality Management System.

Customer Satisfaction

The respondents whose company is General Medical Device manufacturing (4.17) and both (4.16) said customer satisfaction are very high, who are in IVD Medical Device manufacturing (3.67) and others (3.63) said that customer satisfaction are high reference to factors related to Quality Management System.

SUGGESTION:

- Correct QMS Implementation method and Management Representative Knowledge, which leads increase in Quality compliance and proper QMS implementation.
- Continuous Training to all the staffs leads less non conformance and increases productivity
- Management involvement in QMS leads awareness and Quality impact in Quality Management system
- Challenges in implantation overcome by QMS procedure periodic review and continuous training
- Risk based approach in each process leads good QMS implementation follow by increased Productivity.

CONCLUSION:

The conclusion is that when compared with other dimensions on survey with continuous Training has the highest impact with demographic profiles and other factors related to Quality Management System. QMS has no specific destination and its changing limit is also

endless. Organizations always try to improve as well as different techniques and tools such as Implementation method, Risk Based approach and QMS Periodic review invented parallel in QMS. So definition of quality is always evolving. With the intensifying competition, and putting the concept of 'total quality' into QMS practice, it appears that firms which function according to the concept of 'Quality".

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