

COST OF QUALITY: A FORAY INTO SUPPLY CHAIN UPSTREAM

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ABSTRACT

After focusing on COQ at all levels within, the companies now need to move into supply chain upstream as a first step towards addressing COQ-related issues across their supply chains. In this preliminary study, we determine COQ at select third-party contract manufacturing sites of a world leading research-based pharmaceutical company.

Data was collected using the *Traditional Method*, the *Defect Document Method*, the *Time and Attendance Method* and the *Assessment Method* through interviews with internal customers, and check-sheets at the contract sites. Various quality cost elements were identified and categorized under prevention, appraisal, internal failures & external failures.

We estimate quality costs in monetary terms as per PAF model and use standard DMAIC methodology for analysis. We identify significant COQ drivers in this context and suggest measures to address them. Finally, we suggest directions for future research.

INTRODUCTION

It is hard to believe that it has been fifty years since Juran introduced “Gold in the Mine” in which he likened costs resulting in defects to a gold mine in which profitable digging could be done. Since that time, several publications have addressed the topic. Cost of Quality (COQ) is the sum of the costs incurred across a supply chain in preventing poor quality, the costs incurred to ensure and evaluate that the quality requirements are being met, and any other costs incurred as a result of poor quality. The key is to establish a measurement system that can translate COQ into a language of management that every stakeholder can understand. A practical question that arises is how much time and money should managers devote to quality activities within a firm? What about COQ within a supply chain?

As organizations strive to increase their bottom line performance in highly competitive environments, they often forget to integrate two important planning activities, strategic and quality planning. This is likely due to lack of understanding of the cause and effect relationship between strategy, quality, productivity, profitability and competitiveness. To maximize the profits of an organization it is necessary to align the objectives and priorities of the business and the quality improvement process.

How does management currently view the impact of quality on the results of their enterprise? In general, they are aware that quality has some impact on customer satisfaction, but, unless they know that unhappy customers are causing lower sales, some may not be directly concerned. Many realize that quality has an impact on profits, but this understanding may be well focused only when rising costs are due to major quality problems. Management, in general may not directly translate quality or lack of quality into its true impact on their enterprise, yet understanding this impact can easily spell survival in today’s marketplace.

Business processes of the quality management system can be measured in financial terms and the results can be reported to the management and process owners for immediate actions focused on the prevention and continual improvement. The purpose of quality cost techniques is to provide a tool to management for facilitating quality program and quality improvement activities. Quality cost reports can be used to point out the strengths and weaknesses of a quality system.

Improvement teams can use them to describe the monetary benefits and ramifications of the proposed changes. Thus, in practice quality costs can define activities of quality program and quality improvement efforts in a language that management can understand and act on – dollars or any other currency (rupees in Indian context).

We carry out the COQ at select third party contract manufacturing sites of a world leading research-based pharmaceutical company, with an estimated seven per cent of the world's pharmaceutical market. This company is headquartered in Europe with operations based in US. In India, this company's businesses are primarily in the three domains: pharmaceuticals, vaccines and consumer healthcare. The Consumer business in India comprises of Consumer Healthcare Products, Over the Counter (OTC) medicines and Oral Care products.

If we examine the industry scenario, health drinks is a relatively mature category. In the past, the South Indian markets were the high growth markets for white drinks, due to the scarcity of milk. Demand growth in recent times has been driven more by advertising led positioning, coupled with promotional efforts. Major players have repositioned their brands on the health platform in the last few years. Milk/ malted food drinks category is segmented into brown drinks positioned as energy boosters and white drinks positioned as milk substitutes. White drinks account for almost two-thirds of the 90,000-ton market. In the white drink segment, the company's product is the market leader.

LITERATURE REVIEW

While its roots go back to Walter Shewart and others in the 1930's, the modern quality cost system was developed out of the work of Joseph Juran (1951), Armand Feigenbaum (1957), and Harold Freeman (1960). In the 1970's and 1980's Philip Crosby's work helped popularize the cost of quality (COQ) concept beyond the quality profession. According to Crosby, "The only performance measurement is the cost of quality, which is the expense of nonconformance". What costs money is failure to do things right first time.

Multivariate statistical process control (MSPC) techniques and Six Sigma techniques have been extensively used in quality literature. However, COQ has only focused on an Individual firm. In health sector, COQ has been applied for estimation of health care cost drivers, for sales force automation in UK, and so on. Similarly, In the Indian context, Mukhopadhyay (2004) carries out COQ estimation in an Indian textile industry for reducing cost of non-conformance.

Literature describes four categories of costs. Prevention Costs are related to all activities specifically designed to prevent poor quality in products and services. Appraisal Costs are associated with measuring, evaluating, or auditing products or services to assure conformance to quality standards and performance requirements. Internal failures Costs result from products or services not conforming to requirements or customer/user needs (which) occur prior to delivery or shipment to the customer. External failures Costs result from products or services not conforming to requirements or customer/user needs(which) occur after delivery or shipment of the product, and during or after furnishing of a service to the customer. Juran and Gryna (1951) developed a model for categorization of sites which is valid even today. The same is shown in Fig. 1. We utilize the same in our empirical work.

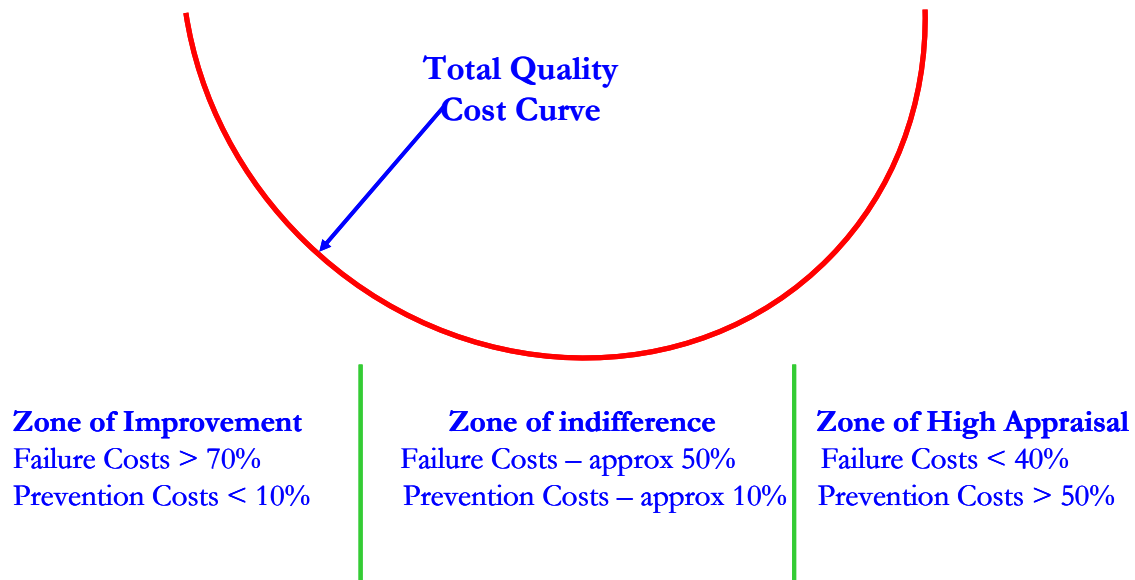


Fig. 1
Model for Categorization of Sites

Zone of Improvement is the left hand portion of the figure. The distinguishing features are that the failure costs constitute more than 70% of the total costs, while prevention costs are less than 10% of the total costs. In such cases there are opportunities for reducing total quality costs by improving the quality of conformance. The approach is to identify specific improvement projects and pursue them to improve the quality of conformance, thereby reducing the costs of poor quality, especially the failure costs.

Zone of Indifference is the central area of the figure. In this zone, the failure costs are usually about half of the quality costs while prevention costs are about 10% of the quality costs. In the indifference zone, the optimum costs have been reached.

Zone of High appraisal costs is the right hand portion of the figure. It is characterized by the fact that appraisal costs exceed failure costs. In such cases also there are opportunities to reduce costs. This may be done by reviewing the quality standards to see if they are realistic in relation to fitness for use. The cost of detecting defects may be compared with the damage done if they are not detected. Now, one should see if it is feasible to reduce the amount of inspection through sampling based on knowledge of process capability and order of manufacture. Similarly, the feasibility to avoid duplication of inspection through auditing of decisions has to be examined.

METHODOLOGY

Quality costs for the sites under study were categorized as per existing literature. Data was collected using the *Traditional Method*, the *Defect Document Method*, the *Time and Attendance Method* and the *Assessment Method* through interviews with internal customers, and check-sheets at the contract manufacturing sites. Literature and discussions with concerned stakeholders were used to identify and categorize various quality cost elements under prevention, appraisal, internal failures & external failures.

Thereafter, we make use of the PAF model to estimate quality costs in monetary terms and use standard Lean Sigma DMAIC methodology and other data analysis tools. We identify significant COQ drivers in this context and suggest measures to address them. Finally, we suggest directions for future research.

DATA COLLECTION AND CATEGORIZATION

Detailed discussions were carried out to ascertain and estimate efforts required in various activities. Check sheets were given to relevant people in third party manufacturing sites. There were a few other sources of data such as MIS reports generated at various 3rd party manufacturing sites and MIS reports generated in the Corporate Quality Department of the firm. Besides, previous years' expense statements which highlight expenses made under various heads viz. training, projects, audits, traveling to resolve customer complaints and various other internal records such as scrap reports and payrolls were also made use of. Besides interviews with internal customers, expert insights were also taken into account.

Thereafter, identification of various quality Cost Elements viz. training costs, rework costs, assessment costs, etc. was done as per literature guidelines and ground realities. The elements of decision flow for this activity are described in Fig. 2. Actual categorization of these cost elements under various heads was done using the PAF Model viz. prevention, appraisal, internal failures & external failures. The PAF model is shown in Fig. 3.

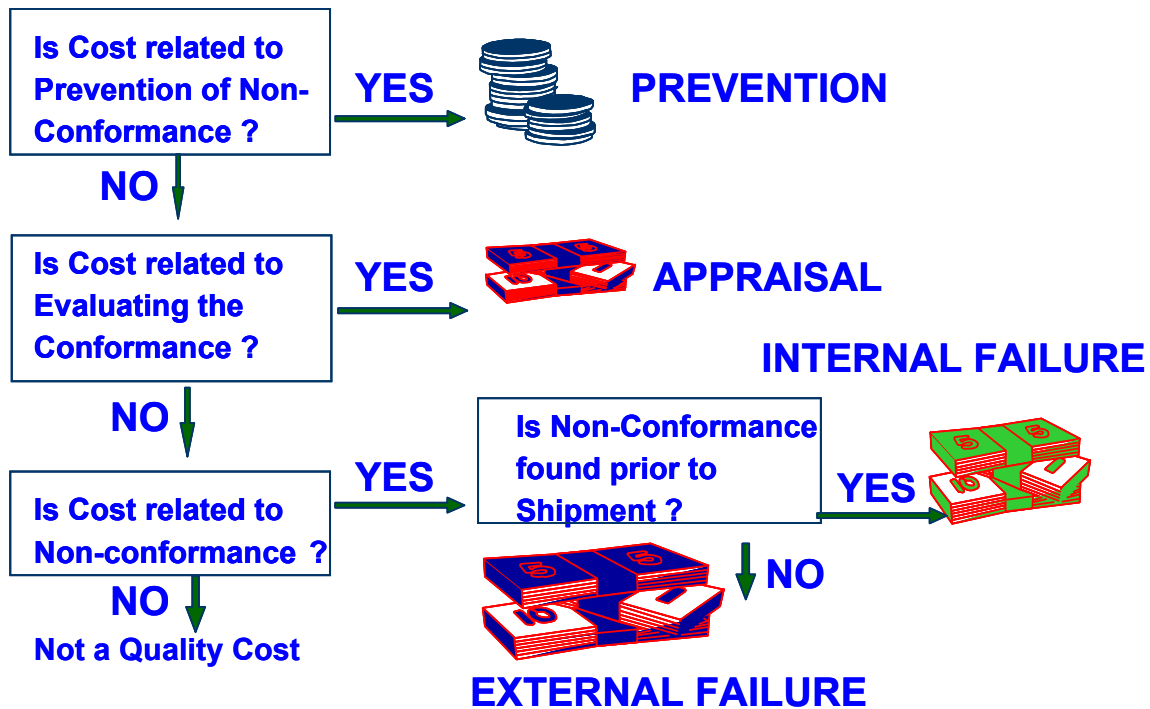


Fig. 2
Elements of Decision Flow

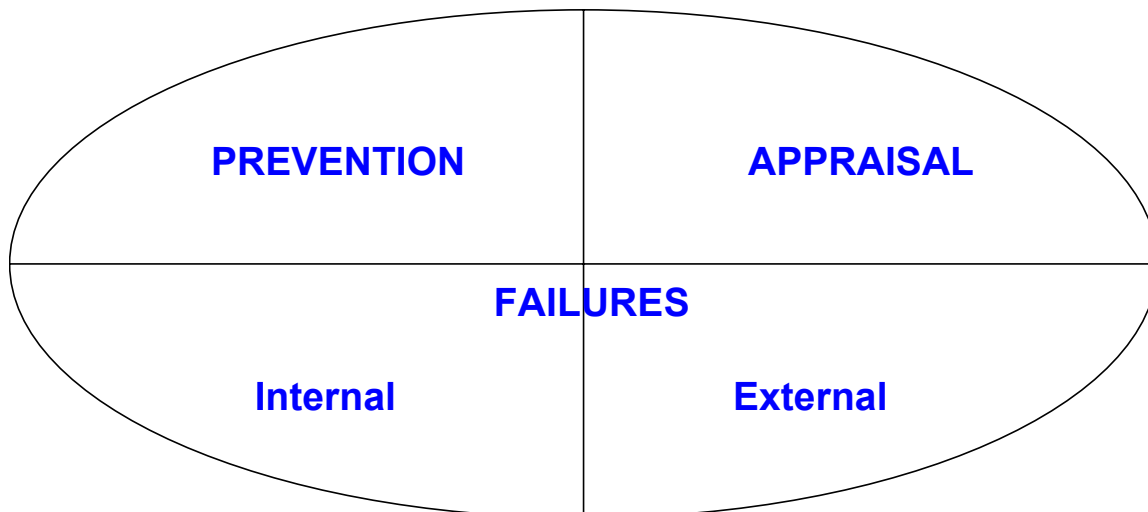


Fig. 3
The PAF Model for Categorization of Costs

Among prevention costs, we considered validations, internal audits, area line clearances, standard operating procedures (sop) generation, change control form (ccf) raising and approval and internal trainings. Validations is a process undertaken to provide high degree of assurance that a facility, laboratory, equipments, computer and systems will consistently and reproducibly produce product, or perform to a predetermined specification. Validation provides a business benefit in those reliable, understood and compliant facilities and processes form the basis for effective manufacturing and control. So as to estimate this cost we've basically considered the efforts (in terms of manpower cost) required to carry out this activity at each site. Review of the quality assurance status of facility, process, utility or system by personnel working at the site is termed as internal audit. Observations during the audit are documented and later recommendations followed up. So as to estimate this cost we've basically considered the efforts (in terms of manpower cost) required to carry out this activity at each site. Area Line Clearance is an activity which is undertaken before any production/packing run at the site so ensure that all materials of the previous run have been removed & cleaned from the line and thus preventing any potential sources of rogues and clearance failures. SOP Generation is an activity undertaken at the site whereby every year due to certain new requirements coming up from the customer or QMS or due to external regulatory issues, etc. certain new operating procedures are required to be made at the sites. The cost of SOP generation has been estimated based upon the number of man-hours and hence the cost required for its generation. CCF Raising and Approval is raised by the originator/owner for any changes warranted in the SOPs, specifications etc. It has to be approved by all relevant stakeholders before the change gets implemented. As per the Pharmaceutical firm's policy, all personnel whose activities may affect GSK product quality must undergo regular appropriate internal training so as to enable them to be able to perform their activities competently. It covers various aspects viz. duty specific training, training on relevant good manufacturing practices, training on company's global quality policies and global quality guidelines and training on hygienic & safety practices, as appropriate. The cost of internal training has been estimated based upon the number of man-hours and hence the cost required for training of personnel at various third party sites.

In appraisal costs, we consider retests and MIS generation. Retest Costs are the costs of carrying out retests in case the first sample taken and the analysis carried out over it doesn't give correct results. MIS Generation Cost has been estimated in terms of number of man-hours spent and the cost thereof in preparing MIS every month.

Internal failures consist of reworks, deviations and concessional approvals. Repeating part of manufacturing process so as to correct a fault in the product is termed as rework. Cost of rework has been estimated by multiplying standard cost of rework for 1Kg of product by the total quantity of product reworked upon in the previous year. At certain sites it has been estimated as the total cost of liaising with different stakeholders so as to get the fault corrected. Deviation is an unplanned departure from SOPs, methods, specifications, protocols, batch records, and other official documents. It can also be defined as departure from instructions, processes, process specifications or normal conditions including any non-conformance or any departure from good manufacturing practices. Deviation Cost has been estimated in terms of number of man-hours spent and the cost thereof in raising a deviation report. In case there's a planned departure from a Standard Operating Procedure, however the implementer based upon risk analysis feels that the action wouldn't have a negative implications on the product. Then, the implementer before going ahead with the implementation has to get approval from the Head of Quality, and the approval form thus raised is called as Concessional Approval Form. Concessional Approval Cost has been estimated in terms of number of man-hours spent and the cost thereof in raising, liaison and approval of Concessional Approval Form.

External failures mainly comprise of customer complaints handling, rodent damage, pouch bursting, expired product in the market and glass bottle breakages. Customer Complaints Handling Cost has been estimated using FMEA (Failure Mode Effect Analysis) tool which in turn calculates the cost of Handling Customer Complaints by estimating the total number of effort hours and thus the cost required to resolve a customer complaint. Rodent damaged product is that product which gets spoiled during storage in depots/wholesaler warehouses etc. GP Bursting is on the account of bursting of pouches in the transit due to improper handling of the product. Expired product in the market captures the total cost of product in the market which becomes unsaleable as it crosses its shelf-life. If the quantity of this product is reduced maybe by better managing the inventory during trade, cost under this category would come. In case of glass bottle breakages 50% of the quantity of product is packed in glass bottles and 50% in pouches. Cost of damage pouches has been captured under the GP Bursting category, while cost of damaged glass bottles during the trade has been captured under this category. This figure has also been obtained from the ERP module of the organization.

Apart from the above described costs, there certain costs on the account of Central Quality costs which for simplicity have been taken as equally distributed across various third party sites.

DATA ANALYSIS AND FINDINGS

Six Sigma DMAIC Process as shown in the Fig. 4 along with inputs from various data analysis tools such as process flow diagrams, histograms, activity based costing, scatter plots, cause & effect diagrams, control charts, pareto principle and check-sheets were used for data analysis on Excel Sheets. The final results of data analysis of various costs are shown in Fig. 5.

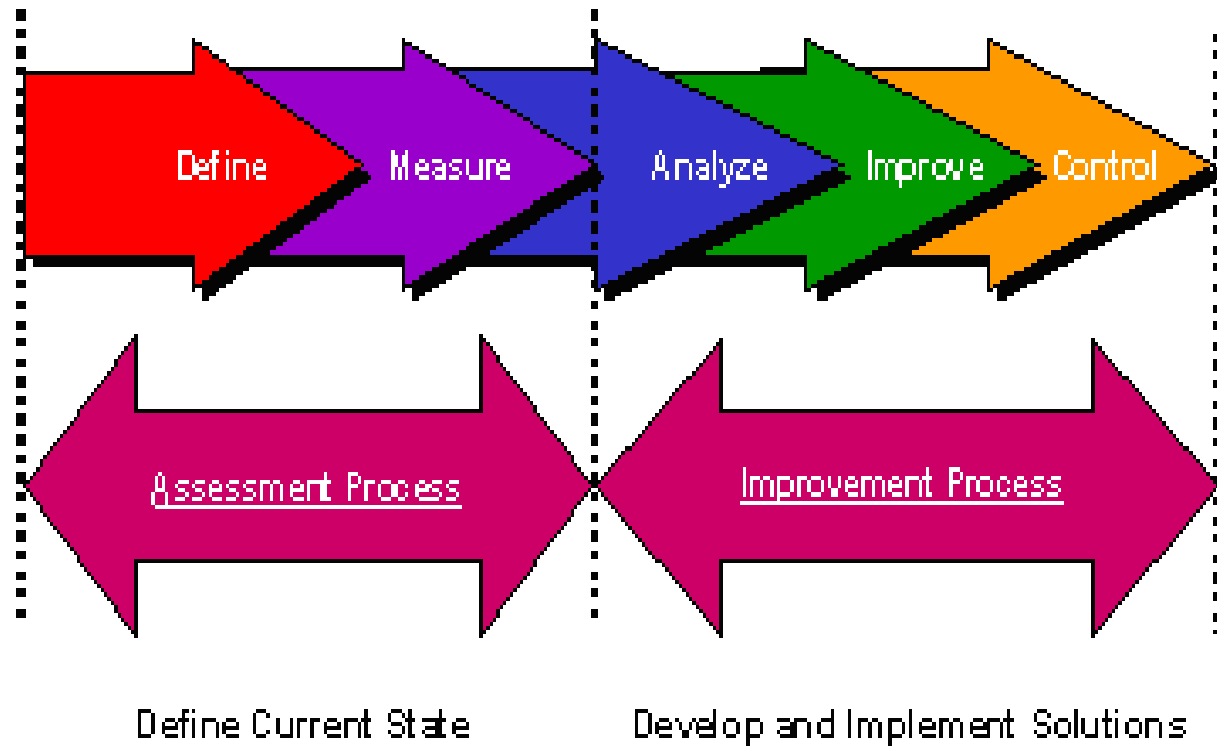


Fig. 4
Six Sigma DMAIC Process

SITE	PC	AC	IFC	EFC	TFC	COQ	(PC+AC) AS % OF COQ
A	570	4.8	54.9	56.4	111.3	686.1	84%
B	519	53.2	14.2	559.5	573.7	1145.9	50%
C	651	53.2	49.4	296.0	345.4	1049.6	67%
D	1030	4.8	3120.8	0.0	3120.8	4155.6	25%
E	400	59.8	79.6	67.8	147.4	607.2	76%

All figures are disguised and in million of INR (Indian Rupees)

Fig. 5
Final Results of Data Analysis of Costs

From the results shown in Fig. 5, we are able to categorize the five contract manufacturing sites as per Juran and Gryna's model and the same is shown in the Fig. 6. This helps to suggest appropriate managerial recommendations.

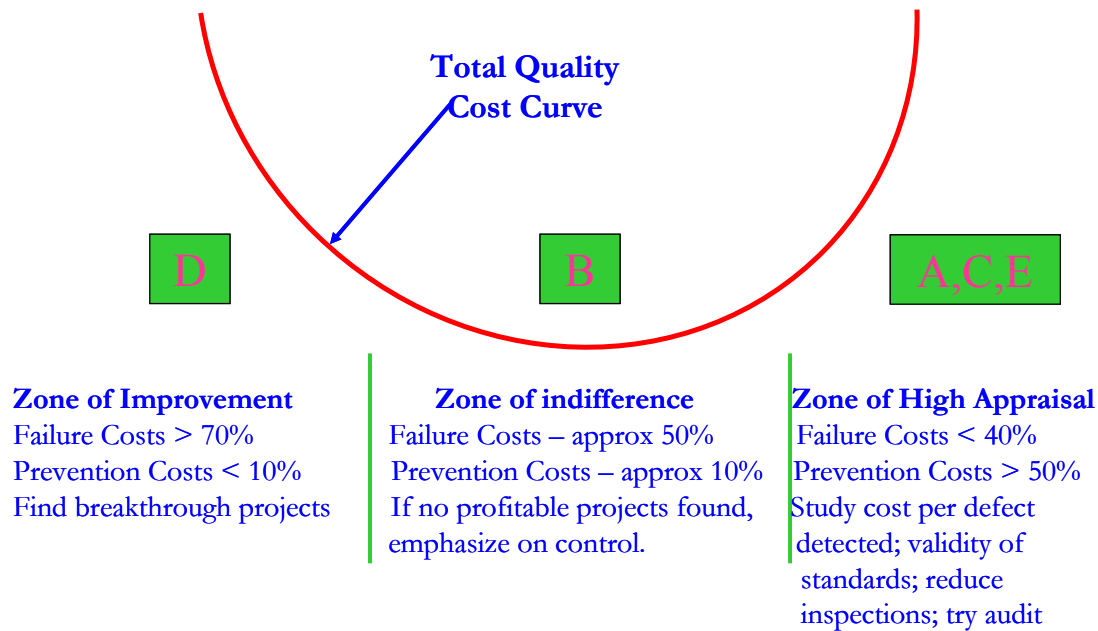


Fig. 6
Categorization of Sites

CONCLUSIONS

We utilized the blend of quality-costing, quality-loss and process-cost approaches to estimate quality costs in monetary terms as per PAF model to judge performance of five third-party contract sites and thereafter categorized them as per Juran and Gryna's model. The study therefore highlights the importance and significance of calculating COQ. It also highlights the costs associated with various activities and non-conformities and elucidates how a COQ system enables to calculate measures of the impact of their quality system on business performance.

Our study not only estimates the size of quality related losses and quantifies the size of the quality problem in the language of money – a lingua franca that improves communication between different stages of supply chain, but also identifies ways of improving quality. It may be used to estimate savings and other benefits. Further, it serves as a successful case history to justify a broader program within the pharmaceutical firm's supply chain.

There are many avenues for potential applications of the study within the company's supply chain. Various cost parameters such as PC/TFC, COQ per Kg of product, etc. can be estimated for different sites/ stages and corrective actions taken. Similarly, other projects may be planned on basis of the categorization as per Total Cost Curve Categorization Model. The firm can develop certain Key Performance Indicators (KPIs) such as quality costs as percentage of sales, ratio of quality costs to profits, quality costs as percentage of cost of goods sold, quality costs as

percentage of Return on Investments (ROI), etc. for internal monitoring or for external benchmarking.

Our study has a few limitations. We have considered only third party contract manufacturing sites and no other facilities in the firms supply chain. Certain cost drivers could not be considered due to insufficiency of data. Further, opportunity cost of lost sales could not be estimated and incorporated in the analysis.

The study provides ample opportunities for future work. The same may be extended to OTC category sites. Similarly, additional cost drivers may be considered. The biggest scope lies in its applicability in other supply chains.

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