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Research Article

Exploring the Role of FMEA in Advancing Continuous Quality Improvement within Micro, Small, and Medium Enterprises

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ABSTRACT

It is extremely challenging but much sought-after in today's globalization era for continuous improvement of product and process quality, particularly for micro, small and medium enterprises (MSMEs). Earlier researchers have proposed a number of tools and techniques for continuous quality improvement (CQI), some of them include lean manufacturing, six sigma, lean six sigma, auto core tools, etc. Few of them succeed and fewer of them do not, particularly in MSMEs. MSMEs encounter usual problems, different than large organization, which disappointed them in attaining CQI by applying these tools. Even in few of the instances, MSMEs are not even aware about these tools, its advantage and how to apply them. The objective of this paper is to analysis the applications and advantages along with available research on Failure Modes and Effect Analysis (FMEA) with specific focus on continuous quality improvement. Methodology adopts a comprehensive review of literature through well-reputed publications- journals, conference proceedings, research thesis, etc. The paper presents an overview of FMEA, enablers, barriers and advantages, and how it developed into sophisticated methodologies to attain CQI in organizations. The objective of this review paper is not to despise FMEA, instead, its aim is limited to present a positive attitude towards FMEA and CQI.

Keywords: Quality Management, Failure Modes and Effect Analysis (FMEA), Automotive MSMEs, Continuous Quality Improvement, micro, small and medium enterprises (MSMEs), Improvement methodology, Automobile Components

I. INTRODUCTION

Big industry growth also generates big competition with the biggest demand from customers, and that intensifies the challenges of survival if unable to supply products with continuous changing quality and price. There are some sectors that can achieve the growth under competitive conditions and some are not. MSMEs with few resources, capabilities and inclinations to enhance make it even more difficult. With the additional task of acquiring perpetual business to sustain, even improving processes continuously so that those improve profits is also crucial.

Explanation of CI is "a company-wide process of focused and continuous incremental innovation (Bessant et al., 1994)" The plan-do-check-act (PDCA) cycle was presented by Dr. Deming as

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the principle of continuous improvement (CI) – quality improvement. Deming explained CI as a philosophy is made up of "Improvement initiatives that increase successes and reduce failures"

Continuous product and process quality improvement is always creative and challenging task in the present era of globalization. Advance quality planning of product and process, prevention of errors by detecting potential failures and statistical controls are highly crucial for continuous quality improvement (Doshi et al. 2016). Different quality tools exist and utilized for the same. Some of them are effective and some of them are not. Given the intricacy in the continuous quality improvement (CQI) process, many new methods are being introduced by the industries and proposed by researchers and academia as well. Lean Manufacturing, Six Sigma, Lean Six Sigma is some of them. In recent times, there are new tools being chosen by the industry, particularly automotive, known as Automotive Core Tools (Doshi J.A. et al., 2017). FMEA is one of the tools which foresees the possible failures and gives chances of elimination. This will enable the companies to realize the continuous improvement in quality, if improvement opportunities found implemented in systematic way. This paper is an effort to address how FMEA can be one of method to realize Continuous quality improvement particularly in micro, small and medium enterprises.

II. FAILURE MODES AND EFFECTS ANALYSIS AND CQI

Most of these ongoing continuous improvement techniques are formed on a fundamental idea of process and quality improvement to minimize waste, streamline the production line and enhance quality. The most commonly used tools for CI include Deming cycle as a four-stage model of quality, the other well-known among them are: lean manufacturing, Six Sigma, balanced scorecard, SPC, MSA, FMEA, and Lean Six Sigma (LSS). Despite the unique strategies to deal with general outstanding control (TQM) applications and bundles, researchers emphasize that in order to achieve excellence, top-level management must care within the software of nice. They firmly advocate that everyone has features, all staff must join inside the development way (S R Patel, et al., 2019).

They show the significance of assessment to have continuous improvement. Continuous improvement of quality can be done by implementing quality improvements that can be identified on the basis of quality tool implementation. Six sigma and lean tools are widely applied in the automobile sectors, but very little work has been conducted in utilizing ACTs – FMEA, SPC, MSA, APQP and PPAP (Doshi J A et al., 2014).

FMEA can take a variety of forms. FMEA's should always be conducted whenever failures would involve possible harm or injury to the end item user. The various forms of FMEA are viewed in Table 1 (Pathak et al., 2011). FMEA is traditionally conducted by a group of members representing all processes of organizations. By their understanding and historical data, risk priority number (RPN) value is being assigned for every failure component (Zhang et al., 2011). Process FMEA focuses on the elimination of challenges related to manufacturing processes. The initial step is to learn and analysis of every step of the manufacturing process and preparation of the flow chart. Then comes the identification of possible failure modes and their respective causes; next, the existing controls are identified, followed by the consequences of failures on the manufacturing line operators and product end-users. The risks of these consequences are then evaluated accordingly (Mariajayaprakash, 2013).

The most important tool is Failure Mode and Effects Analysis (FMEA) for used continuous quality improvement. FMEA is a structured analysis used for identification of failure modes and their effects (Pickard et al., 2005). It is a very prevailing tool, extensively used in manufacturing processes design, to scrutinize failure modes and to reduce effects of respective failures. Hence it helps in identifying measures necessary to improve the product and processes by concentrating on failure modes and its impact (Xiao et al., 2011). The positive results achieved after the solution of problems leads to continuous quality improvement. FMEA may be utilized to identify the root causes of the problem, sometimes a potential problem, as well as the solution to be adopted that will ensure quality improvement (Teixeira et al., 2012).

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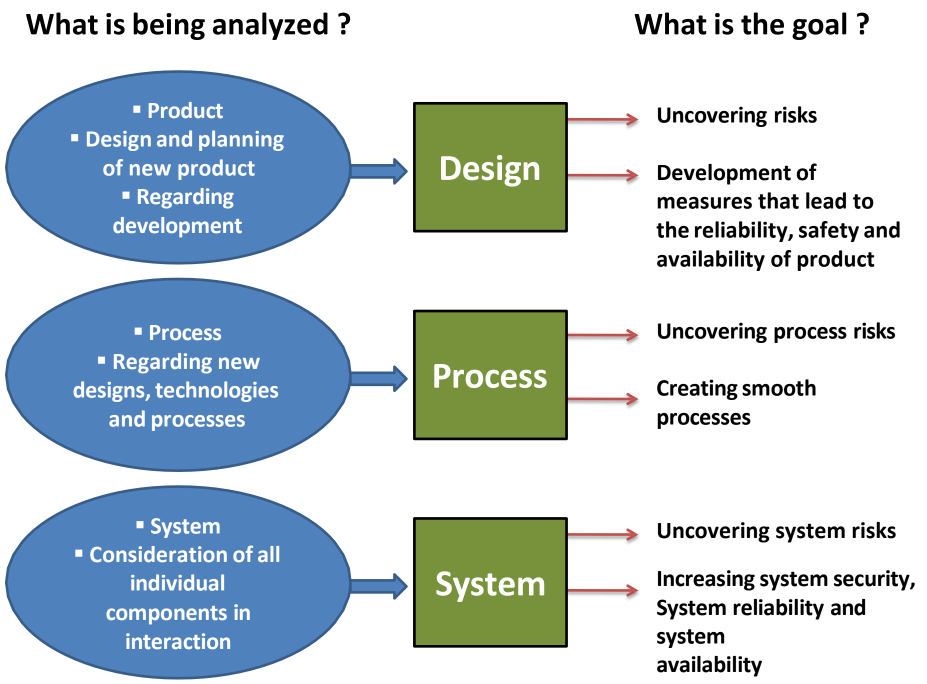

FMEA was mandated as a military regulation in the U.S. The technique was employed as a method of reliability assessment in an attempt to ascertain the impact of disturbances and management, In 1949. Disorders were then ranked based on affect the outcome, individuals, and safety of the equipment. FMEA was adopted and implemented in nearly all sectors since long, in fact, in 1963 NASA had applied FMEA in Apollo project while in 1975 it's applied in nuclear technology and in automobile sector, FMEA was initiated by the Ford motors in 1973 (Korenko et al., 2012). FMEA usage increases opportunities of the improvements and advances integration of employees (Burlikowska, 2011). MSA – Gauge R&R (repeatability and reproducibility) study has been carried out for key to quality (CTQ) characteristics of every company's product and results have been compared. MSA has been used to estimate its effect on product and process quality and external/internal failure, the global effect on CQI. The findings of MSA in four SMEs reveal opportunity for quality improvement; namely in the measurement system – instrument and appraiser. Identified areas for improvement have been implemented within the six-month period that enhances the results to a large extent (Doshi J. A. et al., 2017).

Decision-making in the emergency case is most critical and the same becomes more important for manufacturing. FMEA can detect the related risk with that choice to be resolved in the manufacturing system and implementation stages (Almannal et al., 2008). The final goal of the FMEA is to minimize failure modes and to generate needed quality products. Financial effects of different potential issues in the processes are not directly taken into account, and hence, it was essential to devise a method which would detect and assign priorities to those failures that impact the operation most significantly (Popović et al., 2010). The lacunas of FMEA prioritization approach is as: the same values of RPN can be generated due to severity, occurrence and detection indexes and the team cannot decide the ranking index then accepting average or higher value (Sellappan et al., 2013).

III. FMEA IMPLEMENTATION-CASES

Doshi & Desai (2016) has carried out several case study-based studies in manufacturing MSMEs. The study clearly shows how continuous quality improvement can be achieved through successful application of FMEA in automotive SMEs. The improvement points found and their impact varied for each case company but all the case companies presented continuous improvement in KPIs. The

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improvement was evident both qualitatively and quantitatively. The enhancement in quantative data - KPIs were also varying in case companies, varying between 2-3%. Improvement in rejection and return of goods were very appreciable in each case companies. The improvement being noticed in every case company is in a cumulative manner and is tracked for five months. Another study based on FMEA in foundry proposes reduction in rejections. FMEA was done in core making process to find reasons for rejections of cores and identified most likely reasons for rejections. Solutions to the same were applied and rejection was decreased to 4.2% of total rejection (Pareek et al., 2012). FMEA was done for reliability study of wind turbine system, and comparison was made between quantitative output of FMEA and reliability field data. According to the findings, their relationship was determined that can be utilized for new designs of wind turbines in future (Arabian, et al., 2010). FMEA findings could be utilized for quality enhancement, new designs for future, benchmarking, etc. In the process of manufacturing bearings, there had been different problems eliminated by applying FMEA. In the above-mentioned case study, different causes and their impacts were evaluated for enhancing bearing's reliability. From the risk rating, few of them were suggested in order to bypass the potential risk and thereby reduce the loss to the industries regarding money, time and quality (Thakore et al., 2015). FMEA was applied coupled with AHP analysis for the shell molding process and results reveal a huge amount of rejection decreases from 7.13% to 3.14% (Kamble et. al., 2014). The literature above indicates that FMEA can be applied to process and quality improvement.

Aldridge et al. (1991) applied the application of design and process FMEA at Garrett Automotive Ltd, Skelmersdale. From an analysis of the present methods of preparing and using FMEAs, procedural changes can result in more effective use of the technique. Their findings include the reluctance of product engineering and manufacturing engineering personnel to take a leading role in the preparation of design and process FMEAs, respectively. The main reasons for this related to a perceived lack of time or lack of understanding of the technique's potential. Morello et al. (2008) worked with the development and reduction of a fault tree, applied to gearboxes of heavy commercial vehicles. They claimed that improvement with respect to the classical failure tree analysis (FTA) may be obtained by reducing the number of FTA components based on the sensitivity of the system reliability to the statistical parameters of the components failure models during a certain lifetime. They applied a factorial planning with two replicates to identify the system sensitivity with respect to these parameters taking into account the confidence interval in each case, as the parameters were evaluated from a sample with a specific size, which had a significant influence on the confidence limits. Their methodology allows a reliability model conception for management of the actions focused on products' guarantee and provides design descriptions for the development areas and manufacturing. In their model, it is possible to obtain information about lifetime to assist in activities of performance studies and optimization in design engineering as well as the identification of problems related to design and manufacturing for several operation intervals. Customers demand more variety, better quality, and greater service in terms of reliability and response time. The success in this situation is very much determined by how a company forms the entire system, mainly focusing on supplier management. A supplier plays a very imperative role as the product cost, quality, and service deliverables as they are highly dependent on the supplier performance. Besides cost and quality, an efficient delivery that can respond quickly to the customer demand is also an important issue in the customer-oriented economics nowadays. The need for the development of rudimentary but effective supplier selection method and its implementation is required to improve the product quality and delivery performance, which in turns increases the customer satisfaction (Doshi JA, 2019).

Majumdar (1995) modelled the patterns of failure of a renowned brand of hydraulic excavator system, employed in various environments under a non-homogeneous Poisson process (NHPP), with time-dependent log-linear peril rate functions. Based on the fitted model, he calculated the reliability of the excavator system in various environments (cement plant, coal mine, iron ore mine, etc.). He determined that system is exhibiting extremely poor reliability in the first phase of operation and slowly becomes better with growth in cumulative operating hours irrespective of environment change.

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With the aid of the FMEA method, he detected high risk vulnerable failure modes of excavator system of the mentioned model and proposed necessary corrective actions. The patterns of failure of the improved excavator system varied irrespective of environment, so much so that an HPP (homogeneous Poisson process) model with constant peril rate can be fitted well to describe the pattern of failure of the system. Patel et al. (2005) proposed that every new design has to be tested for failure and reliability, a critical step before approval by the United States Food and Drug Administration (FDA), for clinical testing and use commercially. Due to a greater requirement for effective, reliable, and safe long-term artificial blood pumps. They discovered that the FDA doesn't have established/specific protocols or standards for such testing procedures and there are no more than minimal recommendations coming from the scientific community when an overall blood pump system and specific system components are to be tested. At the design phase of developing blood pumps, FMEA must be done to give a summary assessment of the failure occurrence and frequency and their impact on the overall support system. They also mentioned the research that assesses the failure, reliability, and safety of artificial blood pumps such as in vitro and in vivo testing. A descriptive overview of mechanical and human error studies and artificial blood pump methods is elaborated. S.Deora et al (2012) gave a systematic overview to implement FMEA in software medical devices based on our experience. It also discusses involvement and significance of cross functional team during the design evaluation through FMEA, various challenges that we faced, and how to make a design FMEA successful in lessening the rework and assuring the Product Reliability.

The application of FMEA applied in conjunction with other tools is also extremely useful and casual. FMEA can also be utilized to validate the results of the other tools and additional risk can be corrected. FMEA was utilized as the starting point for a Diagnostic Service Tool to assist in early in the design phase than this being post-production activity (Casea et al., 2010). Arvanitoyannis and Varzakas (2007) used FMEA model for risk analysis of potato chips production. A tentative method of FMEA use to the snack industry is tried in an attempt to examine the critical control points (CCPs) during potato chips processing. Preliminary hazard analysis is applied to predict and analyze the failure modes occurring in a food chain system from the functions, characteristics and/or interactions of the processes or the ingredients on which the system is dependent. CCPs are established and introduced in the cause and effect. They also applied Pareto diagrams for determining the optimal potential of FMEA. Value stream mapping (VSM) is the most critical lean technique that is utilized in the production sector. The value stream mapping that is utilized for the visualization of material flow and collection of information and graphically representing it from the customer end up to the ending process being completed. Methodology of VSM, implementation procedure of VSM, VSM Symbols and VSM Measures, current state to future state map, VSM Tools and some prior work on VSM for continuous improvement (Sultan, et al., 2018). Heising and Grenzebach (1989) quantitatively analyzed and examined the design of the Ocean Ranger offshore oil drilling rig that sank on February 15, 1982 off the coast of Canada. Review of the true disaster was also done based on facts collected by the Canadian Royal Commission. These included the formation of a FMEA table, fault tree, and quantitative analysis with common cause failure of rig elements in risk assessment. In this case of the Ocean Ranger ballast control system, it is shown that the analysis was able both to successfully model the catastrophic system failure of the portholes, the actual system failure mode, and to identify for pump system of common cause failure mode.

IV. CQI FOR AUTOMOTIVE MSMES THROUGH FMEA

One of the most useful tools for improving quality in automotive MSMEs is Failure Mode and Effects Analysis (FMEA). FMEA methodically determines possible failure modes in products or processes and measures their effect, enabling organizations to rank the risks and take corrective action ahead of time. This method not only enhances product quality but also increases customer satisfaction by minimizing defects and increasing reliability

Sustained improvement in product and process quality is a major challenge for micro, small, and medium enterprises (MSMEs), especially in the automotive industry. Such firms usually have limited resources and expertise, which makes it hard to adopt effective quality improvement strategies. Although approaches such as Lean Manufacturing, Six Sigma, and Lean Six Sigma have been brought in to solve these challenges, their success rates in MSMEs have been inconsistent.Integrating FMEA as part of automotive MSME quality management practices presents a systematic approach to potential failures identification and action. Such proactive practice not only improves product quality but also allows for the institution of a continuous improvement culture necessary for competitiveness within the global car industry

V. CONCLUSION

For Good Quality and Trustworthy Products, Customers Are Imposing Greater Expectations on Businesses. There Can Be Problem Solution to Carry Out Continuous Improvement in Quality by SMES. FMEA, SPC Etc. Tools May Be Employed as Sources for Discovering the Problem Source; Can Be Potential Problem, And Means May Be Employed as a Solution That Will Be Path Forward Towards Continuous Quality Improvement (Teixeira Et Al., 2012). FMEA Gives a Simple Method to Find Out Which Risk Is of the Highest Concern and Hence an Action Must Be Taken So That a Problem Does Not Occur. Thus, FMEA Becomes a Good Source for Ongoing Improvement. FMEA Implementation Shall Be Tracked with Time and Efforts Invested Against Benefits Realized. The FMEA Will Outline the Risk Involved in the Process and Their Solutions, But Execution of the Same Has to Be Followed Up. Those Improvement Opportunities Identified Which will Mitigate the Risk, Shall Be Considered as Project – Small, Medium and Large. Each Project and Timely Execution of the Same Has to Be Followed Up. Despite Widespread Research on Individual CQI Methodologies and Various Quality Management Tools Being Created to Measure the Success and Advantages of the CQI Initiative for MNCS or Large Companies, To the Best of the Author's Knowledge, Little Research Has Been Performed in Creating a Framework or Model That Would Facilitate an Organization Identifying the CQI Methodology Suited to Its Requirement.

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