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Failure Modes and Effect Analysis (FMEA) and Continuous Quality Improvement (CQI) – Enablers, Barriers and Benefits

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Abstract: Continuous improvement in product and process quality, especially for micro, small and medium enterprises (MSMEs), is highly difficult and same time much desired in today's era of globalization. In past, researchers had introduced various tools and techniques for continuous quality improvement (CQI), few of them are lean manufacturing, six sigma, lean six sigma, auto core tools, etc. Some of them are successful and few of them are not, especially in MSMEs. MSMEs faces typical challenges, unique than large organization, which let them down in achieving CQI by implementing these tools. Even in few of the cases, MSMEs are not even aware about these tools, its benefits and how to use them. The goal of this paper is to analysis the applications and benefits along with existing research on Failure Modes and Effect Analysis (FMEA) with special emphasis on continuous quality improvement. The methodology uses an extensive review of literature through reputed publications— journals, conference proceedings, research thesis, etc. This paper provides an overview of FMEA, its enablers, barriers and benefits, how it evolved into refined methodologies to achieve CQI in organizations. Objective of this review paper is not to contempt FMEA, rather, its purpose is restricted only to offer a positive view toward FMEA and CQI.

Keywords — Failure Modes and Effect Analysis (FMEA), Continuous Quality Improvement (CQI), micro, small and medium enterprises (MSMEs), Quality Management, Improvement methodology.

I. INTRODUCTION

Rapid growth of the industry also brings high competition through the highest demand of customers, and that increases the difficulties of survival if not able to produce products with continual evolving quality and price. Some industries are able achieve the growth under competitive conditions while others are not. MSMEs having limited resources, competencies and willingness to improve makes more difficult for them. Along with finding continuous business to survival, it is also important to continuously improve processes which in terns improve profits.

The plan-do-check-act (PDCA) cycle was introduced by Dr. Deming as the concept of continuous improvement (CI) – quality improvement principle. Deming described CI is a philosophy as consisting of "Improvement initiatives that increase successes and reduce failures". Another definition of CI is "a company-wide process of focused and continuous incremental innovation" (Bessant et al., 1994).

Continuous improvement of product and process quality is always challenging and creative task in today's era of globalization. Quality planning for both product and process in advance, elimination of errors by identifying potential failures and statistical controls are very essential for continuous quality improvement (Doshi et al. 2016). Various quality tools are available and used for the same. Some of them are successful and few of them are not. Considering the complexity in the continuous quality improvement (CQI) process various new techniques are being introduced by the industries, as well as proposed by researchers and academia. Lean Manufacturing, Six Sigma, Lean Six Sigma is some of the techniques. In recent years, there are new tools being opted by the industry, especially automotive, called as Automotive Core Tools (Doshi J.A. et al., 2017). FMEA is one of the methods which envisage potential failures and provides opportunities for elimination. This shall allow companies to achieve continuous quality improvement, if identified improvement opportunities executed in systematic manner. This paper is

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an attempt to discuss how FMEA can be one of method to achieve CQI, especially MSMEs.

II. FAILURE MODES AND EFFECTS ANALYSIS AND CQI

Many continuously quality improvement methods are established based on a basic concept of quality and process improvement to reduce waste, simplify the production line and improve quality. Among the most widely used tools for CI, Deming cycle is a four-step quality model, the other best known of them are: lean manufacturing, Six Sigma, the balanced scorecard, SPC, MSA, FMEA, and Lean Six Sigma (LSS). Despite the one-of-a-kind tactics to cope with overall excellent control (TQM) implementations and packages, researchers insist that to attain excellence, top management need to be concerned within the software of nice. They strongly believe that everyone features, all personnel must participate inside the improvement manner (S R Patel, et al., 2019). They exhibit the importance of evaluation to achieve continuous development. Continuous quality improvement can be achieved by initiating quality improvements which may be identified based on the implementation of quality tools. Six sigma and lean tools are extensively used in the automobile industries, but very minimum work has been done in using ACTs – FMEA, SPC, MSA, APQP and PPAP (Doshi J A et al., 2014).

FMEA can be of many types. FMEA's should always be done whenever failures would mean potential harm or injury to the user of the end item being designed. The different types of FMEA can be seen in Table 1 (Pathak et al., 2011). FMEA is conventionally carried out by a team of members from all processes of organizations. Using their knowledge and past data, risk priority number (RPN) value is assigned for each failure component (Zhang et al., 2011). Process FMEA concentrates on solving difficulties associated with manufacturing processes. The first step is to study and analysis of each step of the manufacturing process and preparing of the flow chart. Next is to identify potential failure modes and respective causes; then, the current controls are determined, followed by the effects of failures on the manufacturing line operators and product end-users. The risks of these effects are then assessed accordingly (Mariajayaprakash, 2013).

Failure Mode and Effects Analysis (FMEA) is one of the tools used for 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 can be deployed to find the causes of the problem, in some cases a potential problem, along with the solution to be implemented which may improve quality (Teixeira et al., 2012).

Table 1. Types of FMEA

FMEA-TYPES	USAGE
System	Focuses on global system functions
Design	Focuses on components and subsystems
Process	Focuses on manufacturing and assembly processes
Service	Focuses on service functions

In 1949, FMEA was established as a military rule in the U.S. The method was used as a technique for reliability assessment in order to determine the effects of disturbances and management. Disorders were classified according to impact the outcome, people, and safety of equipment. FMEA was accepted and established in almost all industry since long, in fact, in 1963 NASA had used FMEA in Apollo project whereas in 1975 it's used in nuclear technology and in the automobile industry, FMEA was started by the Ford motors in 1973 (Korenko et al., 2012). FMEA application enhances chances of the improvements and advances integration of employees (Burlikowska, 2011). MSA – Gauge R&R (repeatability and reproducibility) study has been conducted for critical to quality (CTQ) parameters of each company's product and results have been analysed. MSA has been utilised to measure its impact on product and process quality and external/internal failure, the overall effect on CQI. The results of MSA at each of four SMEs identify opportunity for quality improvement; specifically in the measurement system – instrument and appraiser. Identified improvement points have been implemented during the period of six months which improves the results significantly (Doshi J. A. et al., 2017).

The decision making in the situation of emergency is very important and the same becomes more crucial in manufacturing. FMEA has the ability to identify the associated risk with that option to be addressed in the manufacturing system and implementation phases (Almannal et al., 2008). The ultimate aim of the FMEA is to reduce failure modes and to produce required quality products. The financial impact of various possible problems in the processes is not directly considered, and therefore, it was necessary to create a method which would identify and give priorities to those failures that have the biggest impact on the operation (Popović et al., 2010). The lacunas in FMEA prioritization method is as: identical values of RPN may be produced as a result of severity, occurrence and detection indexes and the team may not agree on the

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ranking index then approving average or higher value (Sellappan et al., 2013).

III. FMEA IMPLEMENTATION-CASES

Doshi & Desai (2016) has conducted multiple case study-based research in manufacturing MSMEs. The research noticeably demonstrates that continuous quality improvement can be achieved by effective implementation of FMEA in automotive SMEs. The identified improvement points and their effects were different for individual case companies, but all of them showed continuous improvement in KPIs. The improvement was seen qualitatively as well as quantitatively. The improvement in quantitative data - KPIs were also different in case companies, ranging from 2-3%. A very significant improvement in rejection and return of goods were seen in each case companies. The improvement observed in each case company is in a progressive manner and monitored for five months. Another research based on FMEA in foundry suggests a reduction in rejections. FMEA was conducted in core making process to identify the reasons for core rejections and detected most probable reasons for rejections. The remedies for the same were implemented and rejection was reduced to 4.2% of the total rejection (Pareek et al., 2012). The reliability study was conducted for wind turbine system using FMEA, and evaluation was made between the quantitative results of FMEA and reliability field data. Based on the results, the relation between them was established which can use in future wind turbine designs (Arabian, et al., 2010). Results of FMEA can be used for quality improvement, future designs, benchmarking, etc. In bearing manufacturing process, various difficulties had been removed by implementing FMEA. In the said case study, various causes and their effects had been assessed for improving the reliability of bearing. Based on the risk rating, some of the suggestions were proposed for avoiding the possible risk and ultimately decrease the loss to the industries in terms of money, time and quality (Thakore et al., 2015). FMEA was used in combination of AHP analysis for shell molding process and results show a significant reduction in rejection from 7.13% to 3.14% (Kamble et. al., 2014). The above literature suggests that FMEA can be used for improvement in processes and quality.

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 failure patterns of a well-known brand of a hydraulic excavator system, used in different environments with a non-homogeneous Poisson process (NHPP), having time-dependent log-linear peril rate functions. Using the fitted model, he estimated the reliability of the excavator system in different environments (cement plant, coal mine, iron ore mine, etc.). He found that system is having very poor reliability during the initial phase of operation and gradually improves with an increase in cumulative operating hours regardless of change in environment. With the help of the FMEA technique, he identified high risk prone failure modes of the excavator system of the given model and suggested appropriate corrective measures. The failure patterns of the modified excavator system changed regardless of environment, so much so that an HPP (homogeneous Poisson process) model with constant peril rate can be fitted adequately to characterize the failure pattern of the system. Patel et al.

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(2005) suggested that each new design must undergo failure and reliability testing, an important step prior to approval from the United States Food and Drug Administration (FDA), for clinical testing and commercial use. Because of an increased need for effective, reliable, and safe long-term artificial blood pumps. They found that the FDA is not having established/specific standards or protocols for these testing procedures and there are only limited recommendations provided by the scientific community when testing an overall blood pump system and individual system components. During the design stages of blood pump development, FMEA should be completed to provide a concise evaluation of the occurrence and frequency of failures and their effects on the overall support system. They also discussed the studies that evaluate the failure, reliability, and safety of artificial blood pumps including in vitro and in vivo testing. A descriptive summary of mechanical and human error studies and methods of artificial blood pumps is detailed. S.Deora et al (2012) presented a systematic approach to deploy FMEA in software medical devices through our experience. It also addresses involvement and importance of cross functional team during the design evaluation through FMEA, different challenges that we faced, and how to make a design FMEA successful in reducing the rework and ensuring the Product Reliability.

The use of FMEA used with other tools is also very beneficial and informal. FMEA can also be used to authenticate the outcomes of the other tools and further risk can be remedied. FMEA was used as the beginning for a Diagnostic Service Tool to support in early in the design process than this being post-production action (Casea et al., 2010). Arvanitoyannis and Varzakas (2007) applied FMEA model for the risk assessment of potato chips manufacturing. A tentative approach of FMEA application to the snacks industry is attempted in order to analyze the critical control points (CCPs) in the processing of potato chips. Preliminary hazard analysis is used to analyze and predict the occurring failure modes in a food chain system based on the functions, characteristics and/or interactions of the ingredients or the processes, upon which the system depends. CCPs are identified and implemented in the cause and effect. They also used Pareto diagrams for finding the optimized potential of FMEA. Value stream mapping (VSM) is the most essential lean technique which is used in the production industry. The value stream mapping which is used for visualizing the flow of material and gathering the information and representing it graphically right from the customer end till the end process is fulfilled. Methodology of VSM, implementation procedure of VSM, VSM Symbols and VSM Measures, current state to future state map, VSM Tools and some previous work on VSM for continuous improvement (Sultan, et al., 2018). Heising and Grenzebach (1989) studied and analysed quantitatively the design of the Ocean Ranger offshore oil drilling rig that capsized and sank on February 15, 1982 off the coast of Canada. A review of the actual disaster was also included based on evidence gathered by the Canadian Royal Commission. They included the construction of a FMEA table, a fault tree, and a quantitative evaluation including common cause failure of the rig components in the risk analysis. 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 a common cause failure mode of the pump system.

IV. CONCLUSION

Customers are placing increased demands on companies for high quality and reliable products. Continuous quality improvement can be done through problem solution in SMEs. FMEA, SPC and other tools can be used as sources to identify the sources of problem; may be potential problem, and methods can be deployed as a solution which will be way forward to continuous quality improvement (Teixeira et al., 2012). FMEA provides an easy tool to determine which risk has the greatest concern and therefore an action is needed to prevent a problem before it arises. Hence, FMEA becomes good source for continuous improvement. The implementation of FMEA shall be monitored for time and efforts given against the benefits achieved. The FMEA will identify the risk associated with the process and their remedies, but the implementation of the same needs to be monitored. Identified all improvement opportunities which will reduce the risk, shall be treated as project – small, medium and big. The monitoring of each project and timely completion of the same is important. Although much research has been conducted on the individual CQI methodologies and quality management tools have been developed to determine the progress and benefits of the CQI initiative for MNCs or large companies, to the author's knowledge, little focus has been directed towards developing a framework or model that would enable an organisation to identify the CQI methodology that best suits its needs for SMEs.

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