Chapter 13
Fuzzy Failure Mode and Effects Analysis in a Pharmaceutical Production Process With Fuzzy PROMETHEE Method

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ABSTRACT

Failure mode and effects analysis (FMEA) is a quality improvement technique that defines potential errors and ranks them according to their degree of effectiveness in both service and production processes. While enterprises want to produce quality products or services, they also strive to reduce the cost of quality. At this point, the FMEA method provides a proactive approach to decision makers by ensuring that the types of errors in products sent to both internal and external customers and the probability of occurrence of these errors are predicted. In recent years, the FMEA method has begun to be evaluated in the frame of fuzzy logic to obtain more effective results. In this way, results have become realistic and objective. This chapter analyzes pharmaceutical production process to define potential error types and the effect of these errors. Risk priority order of error types is determined by Fuzzy PROMETHEE Method.

INTRODUCTION

In recent year, firms have entered into a challenging struggle for competition, due to the rapid development of technology and the change in customer understanding. Firms have to differentiate with the products or services they offer in order to be able to survive in intense competition conditions. In addition, it has become a necessity for them to develop themselves. One of the important points that firms can make a difference is the quality of the product or service. Observing errors which causes the fail of the production processes and taking corrective actions in every process ensures the quality of the final products that will go to the external customer while increasing the quality of the products used by internal customers. Also these errors can lead to defects and waste outcomes for the customers. Preserving and improving the

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quality level is closely related to the design of the product, the production process, and the sales process. In order to create customer satisfaction, the operation of all these processes should be planned correctly.

The main objective of this chapter is to propose a practical and efficient model to determine the potential failure types in a pharmaceutical process and, rank them according to the RPN number using a multi-criteria decision-making (MCDM) method. In this study, firstly, a fuzzy approach, allowing decision makers to use linguistic variables for determining the weights of risk factors: severity (S), occurrence (O), and detectability (D) is considered for FMEA. Then, failure types in the pharmaceutical process are evaluated according to the RPN values using the Fuzzy PROMETHEE method. This proposed model permitting the use of different importance weights for the risk factors (S, O, D) in fuzzy PROMETHEE for scoring and sorting of the potential failure modes, can be taken as a contribution in the Fuzzy FMEA literature. Also, there is no research implements the Fuzzy PROMETHEE to improve the FMEA for a pharmaceutical process. Therefore, there is a necessity to present a risk sorting model for FMEA by including the advantages of the Fuzzy PROMETHEE method.

In this study, pharmaceutical production, which is one of the most important actors in the health sector, has been selected. Pharmaceutical production involves crucial processes related to human life. Therefore, Good Manufacturing Practice (GMP) which is a set of rules and practices that minimize production risks and failures, is implemented in pharmaceutical production. This rules system requires process-oriented operations from raw material procurement to final product packaging. Process –oriented operations are carried out with standard operations procedures (SOP) which is unchanged rule of GMP. The SOP is a guideline to apply every operation in the production process in the same way. All of the production processes are performed and followed in accordance with the quantity and quality written in the SOP's. In this way, risks and failures lead to variability and deviation in production can be prevented. Therefore, pharmaceutical companies have to comply with GMP standards to deliver the guaranteed full product to the customer.

Nowadays, the FMEA method has been widely used to determine potential errors which cause variability and deviation and its' impactsin the pharmaceutical processes. FMEA method has emerged as a quality improvement technique for prevention before errors occur. FMEA focuses on the risks that may cause poor quality in production processes. The traditional FMEA method prioritizes the types of failure by determining the risk priority number (RPN) of the failure types. In other words, it ensures the types of errors that may contain high risk or danger are considered as a priority (Şimşir, Demir, & Azdemir, 2018, p.24).

When the studies in the literature are examined, it has been determined that the traditional FMEA technique has some deficiencies which are described under the Fuzzy FMEA title of this study. for real-life problems. These deficiencies are mostly related to detection and evaluation o frisk factors which is showed S, O, and D. Several methods have been proposed in the literature to eliminate these deficiencies. One of these methods is to combine the FMEA with MCDM techniques.

Some Studies which combine AHP (Analytic Hierarchy Process) with the FMEA technique in the literature: Braglia (2000) developed a multi-feature error analysis method that works based on AHP technique. According to the study, risk factors is decision criterion, error causes are decision alternatives and priority order of error causes are accepted as objective function.Hu et al. (2009) determined the relative weight of risk factors by the Fuzzy AHP method and proposed the green component risk priority number for the analysis of hazardous substances in green components. Shahrabi and Shojaei (2014) attempted to identify the root causes of failures in one of the oldest refineries in the world by using FMEA and AHP techniques and to minimize these expenditures. IIlangkumaran et al. (2014) proposed a