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Failure Mode Assessment in Production Line by Using FMEA and RPN Method

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Abstract – The risk management program comprises of four main components: risk control, risk assessment, risk communication, as well as risk review. Each four component is crucial. All the above methods should address on the mentioned four basic components. Team selections as well as technique selection have also been playing an important role in the risk management process, so attention should be given while assortment of risk management team as well as approaches. FMEA has been a better approach for risk management in the pharmaceutical industry by means of FMEA analysis comprise greater reliability, better quality, enhanced safety as well as its contribution for cost saving comprises reduced development time as well as lessened waste and non value added processes. Conventional FMEA has some shortcomings, and in this work, it has been improved by improving the RPN number and optimizing results of production line.

Keywords: Risk Management; Failure modes and effect analysis (FMEA); Risk Priority Number (RPN), Revised RPNs, Pharmaceutical Industry

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INTRODUCTION

Failure Modes and Effects Analysis (FMEA) has been a methodical, proactive approach for assessing a process to recognize where as well as how it might collapse and to evaluate the relative influence of different failures, to recognize the parts of the process that are greatest in need of modification. FMEA comprises review of the following:

Failure modes (What is supposed to go wrong?)

Failure causes (What are the possible reasons of failure?)

Failure effects (What would be the effects of each failure?)

Teams use FMEA to assess processes for probable failures as well as to avert them by amending the processes proactively preferably than reacting to unpleasant events after failures have happened. This stress on prevention may lessen risk of damage to both patients as well as staff. FMEA has been particularly useful in assessing a new process erstwhile to execution as well as in evaluating the impact of a suggested change to a current process [1].

In earlier days risk in the product quality and process had been assessed in the following informal ways.

- Trends review
- Check lists
- Flow charts
- Observations accumulation [From complaints, deviations etc.]
- Changes review

Nowadays the risk management method started by regulatory agencies along with renowned management tools with backing of statistical tools in amalgamation, which make comfortable for application of quality risk management principles throughout the industry. A Risk Management Program begins with recognizing the probable risks related with a product or may be with the process utilized to develop, manufacture, as well as dispense the product. An efficient quality risk management safeguards the great quality of drug product to the patient. In adding up quality risk management enhances decision making if a quality problem ascends. It should comprise systemic

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processes elected to co-ordinate, facilitate as well as enhance science-based decision-making along with respect to risk.

Risk Management Methods

To achieve risk-based decisions, a systematic method is important. The ICH Q9 guideline, Quality Risk Management, delivers a structure to begin, as well as trail a risk management process. The following approaches broadly used in the industry aimed for risk management.

- Basic risk management facilitation approaches (flowcharts, check sheets, etc.)
- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects, and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP)
- Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Risk ranking and filtering
- Supporting statistical tools[2]

Table 1 Risk Management Methods

No.	Method	Area of Application
1	Basic risk management methods. Flow charts/Process mapping, Check lists, Cause & Effect diagrams	Data organization to enable decision making in the areas of 1.Failure investigations 2.Root cause analysis
2	Failure Mode Effects Analysis (FMEA)	Equipment and amenities which are concerned in the manufacturing.
3	Failure Mode, Effects, and Criticality Analysis (FMECA)	Risks related with manufacturing process.
4	Fault Tree Analysis (FTA)	Root cause evaluation as well as failure investigations
5	Hazard Analysis and Critical Control Points (HACCP)	Supervising of critical points not only in the manufacturing process but also in further lifecycle phases.
6	Hazard Operability Analysis (HAZOP)	Manufacturing processes, assessing process safety hazards.
7	Preliminary Hazard Analysis (PHA)	Analyzing current systems or prioritizing dangers as well as commonly used prematurely in the development.
8	Risk ranking and filtering	Prioritize manufacturing sites for scrutiny /audit by Regulators or industry, to assess both quantitatively-assessed and qualitatively-assessed risks in the interior of the same organizational framework.
9	Supporting Statistical Tools	Data assessment.

QRM PROCESS

Initiating a QRM process: QRM activities should be functioned using systematic procedures designed to coordinate, facilitate and improve science-based decision-making with respect to risk. Probable steps used to begin as well as plan a QRM process might comprise the following (Ref. ICH Q9):

- describe the obstruction and/or risk question, counting pertinent assumptions recognizing the potential for risk;
- assemble backdrop information and/or data on the potential hazard, damage or human health influence pertinent to the risk assessment;
- recognize a leader as well as necessary resources; and
- specify a timeline, deliverables and appropriate level of decision-making for the risk management process.

Personnel involved in QRM: The executing party, i.e. pharmaceutical manufacturer or supervisory authority, should guarantee that personnel along with suitable product-specific knowledge as well as expertise are obtainable to safeguard effective planning as well as completion of QRM activities. The personnel should be able to:

(a) Perform a risk analysis. (b) Identify as well as analyze potential risks. (c) Recognize, evaluate risks and regulate which ones should be coordinated and which ones can be taken; (d) Endorse as well as implement adequate risk control measures. (e) Develop procedures for risk review, monitoring and confirmation.

Knowledge of the product and process: Any action of QRM would need to be built on knowledge of the product or processes bothered, according to the phase of the product life-cycle. Where necessary, a flow diagram might be beneficial, obscuring all operations as well as manages in the process under assessment. When smearing QRM to a given operation, the steps heading as well as following that operation should also be considered. A block-type diagram may be

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adequately illustrative. Amendments to the flow diagram may be created were suitable, and should be recorded.

Risk assessment: When risk assessment is performed safety as well as efficiency needs to be measured in addition to the quality concerns. Throughout the evaluation all the risks that may be sensibly expected to happen in the activity under assessment should be enumerated. This is usually operated during its beginning when there is an alteration or a apprehension and may also be operated to existing processes. An analysis should be performed to recognize which risks have a nature that their eradication or lessening to acceptable levels is indispensible. A thorough risk analysis is required to ensure an effective risk control. It should review the materials, activities, equipment, storage, and spreading as well as envisioned usage of the product. Usually a list of the potential risks (biological, chemical as well as the physical) which may be presented, augmented or regulated in each step should be drawn up. In case of risk analysis certain basic questions must be talked about and here are the following:

What is the type of possible risks?

What is the possibility of their happening and how well it would be to identify them?

What are the outcomes (the severity)?

It should then be obvious which potential risks should be tackled by the QRM activities as well as what regulatory measures, if any, should be implemented for each risk. If a risk is recognized at a step where control is essential for safety, as well as no control measure occurs at that step or at any other, the product or process should be improved at that step, or at a previous or later stage, to comprise such a control measure. Greater than one control measure might be needed to regulate a specific risk as well as greater than one risk may be regulated by a specified control measure. Risk assessment could be simplified through the use of a decision-tree, which assisted a logical method. The manner in which a decision-tree is utilized will be contingent on the operation concerned. Usually, potential risks in association to the following should be counted:

– Materials and ingredients; – physical characteristics and composition of the product; – processing procedures; – microbial limits, where applicable; – premises; – equipment; – packaging; – sanitation and hygiene; – personnel – human error; – utilities;

Risk control: Risk control has been a decision-making activity designed to lessen and/or receive risks. It typically happens after risk assessment, as well as at an essential level its reason is to lessen the risk to a satisfactory level. Throughout risk control activities the following major questions should be asked:

What could be done to lessen or eradicate risks?

What is the suitable balance among profits, risks and resources?

Are new risks presented as a consequence of the recognized risks being regulated?

Risk control activities normally include recognizing controls as well as the measures which might lessen or regulate the risk related with a failure mode or negative event. Risk control activities could serve to govern critical process parameters for certain controls, how they would be supervised, as well as the level of qualification and validation which might be needed, if any, for such controls [3].

Risk review: Suitable systems should be at spot to safeguard that the outcome of the QRM process has been periodically supervised and reviewed, as suitable, to evaluate new data that may influence on the original QRM decision. Instances of such changes comprise of changes to control systems, changes to equipment as well as processes, alterations in suppliers or contractors as well as organizational restructuring. Supervising has been the scheduled measurement or scrutiny of a specific risk control measure kin to its acceptance limits. Supervising should be noted. All records as well as the documents related along with risk review should be signed as well as dated by the person(s) performing the review and through a responsible official(s) of the quality unit of the company.

LITERATURE REVIEW

(Soewardi and Wulandari, 2019) [4] Sugar has been the regular basic requirement of human life. It is made up of cane trees then, manufactured using a milling machine in the initial phases. This machine has been functioned 24 hours each day; therefore, it should be in a good condition as well as the company must be capable to safeguard the machine so that, it can run fine by scheduling daily maintenance. This study aimed to investigate the potential failure of manufacturing process to provide some recommendations for improvement. Failure Mode and Effect Analysis (FMEA) method was applied to analyze the situation, and Logic Tree Analysis (LTA) was implemented to classify the types of improvement. Meanwhile, the classification of improvement consisted of 3 categories namely safety problem (A), outage problem (B), and economic problem (C).

(Josiah, Keraita and Muchiri, 2018) [5] This study focuses on recognizing and arranging priority wise critical recurrent as well as potential failures in corn milling plants using chosen control parameters by

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the application of FMEA for reasons of enhancing critical milling plant sub systems reliability. This research assessed a corn milling plant's critical sub-systems failure modes as well as determined that corn milling plants have important sub-systems along with critical failure modes whose failure outcome produced prolonged downtime as well as elevated downtime cost. This study gives a frame work for corn milling plant failure modes recognition and prioritization for reasons of failure eradication to improve milling plant equipment obtainability.

(Baynal, Sari and Akpinar, 2018) [6] Failure modes and effects analysis (FMEA) approach is a risk management device to stabilize production as well as improve market competitiveness by using risk priority numbers (RPN). The reason behind this paper is towards contributing to risk management activities by proposing solutions to assembly line challenges in an automotive manufacturing company through usage of combined GRA and FMEA method. In the suggested approach, the priorities of production failures have been established by GRA approach as well as such failures were minimalized by using FMEA method. The study outcomes showed the actions that caused improvement in the product.

(Doshi and Desai, 2017) [7] The reason behind this research paper has been to stage the impact of FMEA to accomplish Continuous Quality Improvement (CQI) by multiple case study research. The result research conducted through implementing FMEA; one of the Auto Core Tools (ACTs), in the automobile Small as well as Medium Enterprises (SMEs) in Gujarat, India is given in these papers which depict various means of Continuous Quality Improvements. The case study grounded research was performed in four automobile SMEs; all of them are delivered to automotive Original Equipment Manufacturer (OEM). The FMEA was executed with the help of Cross Functional Team (CFT) to recognise the potential failure modes and effects, in overall influence on Continuous Quality Improvement.

(Nguyen, Shu and Hsu, 2016) [8] To accomplish the current gap in the FMEA literature, this paper suggests an extension through considering related quality cost as well as the ability of failure detection system as additional determinants to indicate the priority level per failure mode. Analytical outcomes show that the suggested method overtakes the traditional one as well as remarkably lessens the percentage of defective fabrics from about 2.41% before the trial period to 1.13%, thus effectively decreasing wastes as well as augmenting operation efficiency, thus delivering valuable benefits to enhance organizational competition power for their sustainable development.

(Pawar and Rathod, 2016) [9] This research work goals to recognize and eradicate potential as well as present problems from a manufacturing process of mixed model assembly line in automobile industry by the implementation of failure mode and effect analysis (FMEA).A Process Failure Mode Effect Analysis (PFMEA) is a systematic tool operated by an organization ,business unit to recognize as well as assess the potential failures of a process .PFMEA aids to determine the impact because of failure ,and recognize and calculate the action items with the aim of lessening risk. It has been a dynamic document that should be started before process of production as well as preserved throughout the life cycle of the product.

(Shinde, Shrivastava and Morey, 2015) [10] Manufacturing practices incline to produce defects because of several causes, which can be enhanced through recognizing as well as eradicating them using six sigma. In the current study, DMAIC (Define, Measure, Analyze, Improve and Control) is used for decreasing the total of bush rejection. In case of define phase problem has been described by picking the core issues concerned. Next, in case of measure phase data has been collected to govern the current performance as well as the process competency. In analyzing phase root causes of bush rejection have been recognized.

(Degu and Moorthy, 2014) [11] Failure Mode and Effect Analysis (FMEA) has been a pro-active class tool for assessing potential failure modes as well as their grounds. It aids in prioritizing the failure modes, and then suggests counteractive measures for the escaping of catastrophic failures and improvement of quality. In this study, an effort is being made to execute Machinery FMEA in UPVC pipe production division of Amhara Pipe Factory, P.L.C., Bahir Dar, Ethiopia. The failure modes as well as their causes have been recognized per machine, the three major indices (Severity, Occurrence and Detection) we reconsidered and the analysis has been performed by the help of MFMEA Worksheet.

(Ozilgen, 2012) [12] The Failure Mode and Effect Analysis (FMEA) has been smeared for risk assessment of confectionary manufacturing, where the traditional approaches as well as equipment have been intensively used in the production. Potential failure modes and effects as well as their probable reasons recognized in the process flow. Processing that include intensive handling of food by the hand of workers had the greatest risk priority numbers (RPN = 216 and 189), trail by chemical contamination risks in distinct stages of the process. The function of corrective actions considerably decreased the RPN (risk priority number) values.

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MATERIAL AND METHOD

Basic risk management facilitation methods:

The plain method used to structure risk management through organizing data as well as simplifying decision-making are flow charts, check sheet, process mapping, causes as well as the effect diagrams.

Failure Mode Effects Analysis (FMEA):

FMEA depends on product as well as process understanding. It methodically breaks down the analysis of complicated processes into practicable steps. It gives assessment of potential failure modes for processes as well as their likely result on product performance. It could be functional to equipment as well as facilities and might be utilized to analyze a manufacturing operation as well as its influence on product or process. This tool is more advanced along with studying criticality of the outcomes as well as giving clear indication of situation. The reason, terminology as well as other details can differ conferring to type (*e.g.* Process FMEA, Design FMEA, and Health FEMA etc.), the rudimentary methodology is alike for all.

Benefits of FMEA : Certain advantages of operating FMEA analysis comprise advanced reliability, improved quality, amplified safety as well as its input for cost saving contains reduced development time as well as decreased waste and non value added operations. Cost advantages related with FMEA are typically anticipated to come from the skill to recognize failure modes former in the process, when they are less costly to tackle. Financial advantages have also been arisen from the design enhancements that FMEA is anticipated to enable, counting decreased warranty costs, amplified sales by improved customer satisfaction, etc.

This gives a studying tool for fresh engineers as well as encounters customer necessity and/or to obey with Safety and Quality needs, such as ISO 9001, QS 9000, ISO/TS 16949, Six Sigma, FDA Good Manufacturing Practices (GMPs), Process Safety Management Act (PSM) Ideally, FMEA is best done in conjunction with or soon after PHA efforts. Outcomes may be used to recognize high-susceptibility elements as well as to direct resource deployment for best advantage. An FMEA could be done whichever time in the system lifetime, from first design onward.

Failure Mode, Effects and Criticality Analysis (FMECA):

It has been the addition of previously said FMEA tool. Spreading FEMA to integrate an exploration of the degree of severity of outcomes, their possibilities of happening as well as their detectability has been Failure mode, effects as well as criticality analysis. In FMECA, every failure mode of the product is recognized and then assessed for criticality. Such criticality is then interpreted into a risk, and if this altitude of risk is not tolerable, corrective action must be grabbed. This can be applied for failure and risk associated along with manufacturing processes. The device can also be utilized to establish and optimize maintenance plans for repairable systems and/or contribute to control plans and other quality assurance procedures. In adding together, an FMEA or FMECA is often essential to comply along with safety as well as quality necessities, for instance ISO 9001, QS 9000, ISO/TS 16949, Six Sigma, FDA Good Manufacturing Practices (GMPs), Process Safety Management Act (PSM), etc. When we execute a FMECA, we are recognizing all potential failure modes as well as their related influences. To make this task more controllable, we must primary decide what kind of FMECA we need to apply - Design, Process, User, Software, Test, to term a few.

Severity classification

This classification has been allotted to deliver a qualitative measure of the poorest potential consequences resulting from design error or item failure. Classifications should be allotted to all identified failure mode as well as each item analyzed in agreement with the loss statements below. It may not be likely to recognize an item or a failure mode conferring to the loss statements in the four categories described below, but alike loss statements based on several contributions as well as yields can be developed and comprised in the base rules for the FMECA activity. Severity classification categories that are reliable along with have been well-defined as follows:

Category I–Catastrophic – A failure that may cause injury or death.

Category II–Critical – A failure which might source plain injury, main property harm, or chief stem damage that will end in major downtime or production loss.

Category III–Marginal – A failure which may source slight injury, slight property harm, or slight system damage which will end in delay or loss of system availability or degradation.

Category IV–Minor – A failure not grave enough to source injury, property harm or system damage, but will end in unprepared maintenance or overhaul.

Fault tree analysis (FTA):

FTA is a device which supposes failure of the functionality of a product or procedure. The

consequences are signified pictorially in the shape of a tree of fault modes. This can be used to examine complaints or divergence in order to completely comprehend their root cause as well as safeguard that envisioned enhancement will determine the issues and not source any other special problem. A good Hazard Analysis as well as critical control points (HACCP) are:

HACCP has been an organized, proactive and precautionary tool for promising quality, reliability and safety. It includes hazard analysis, determining critical control point, establishing critical limit, determining a system to supervise critical control point as well as determining a record preserving system. This might be utilized to recognize and handle risk related with physical, chemical as well as biological hazards.

Hazard operability Analysis (HAZOP): HAZOP remains a greatly structured hazards recognition tool. This is based on assumption that events have been sourced by deviations from the design or operating purposes. The purpose and scope of the study should be determined before a HAZOP Study objectives may be to observe the security of the design, choose whether and where to build, inspect operating as well as safety procedures, enhance the security of a present and improved facility, and confirm that safety instrumentations are operating optimally. HAZOP Methodology includes collection of document and drawing, breaking facility into manageable section, listing out parameters, create deviations, record cause and consequence for each cause, record controls to prevent the cause and list any future action that should be implemented. It is imperative that accurate information associated with the project is sourced as well as encompassed in the study. Such information may include provisional layouts, material safety data sheets (MSDS),process flow diagrams, plant model, equipment arrangement drawings, provisional operating instructions, heat and material balances layouts, logic diagrams, equipment datasheets, hazardous area layouts, and start-up and emergency shutdown procedures.

Preliminary hazard Analysis (PHA):

This tool analysis has been based on harnessing prior familiarity or knowledge of hazard to recognize future hazards, hazardous condition. This can be utilized for product, process and facility design. This can be utilized in early development of a project where there is little information on detail is available. Preliminary hazard analysis (PHA) has been a semi-quantitative analysis specifically implemented to recognize all potential hazards as well as accidental incidents that may direct to an accident. Rank the recognized accidental incidents rendering to their Severity as well as identify needy hazard controls and follow-up actions.

QUALITY RISK MANAGEMENT INVESTIGATION

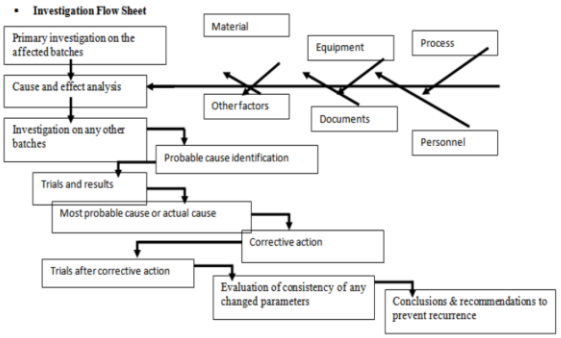

Fig. 1 Quality Risk Management Investigation

QRM IN PHARMACEUTICAL PRODUCTION

QRM principles applied as a process reinforces science-based as well as practical decisions when combined into commercial manufacturing. In general applying QRM should not avoid a manufacturer's responsibility to obey with supervisory expectations (e.g. regulatory requirements, regulatory filings, inspection commitments, etc.). All QRM activities should be organized in a manner that permits escalation of risks to the appropriate management level within the organization. Specific emphasis can be on the risk evaluation as well as risk control of, e.g.:product quality risks; unfavorable influence to patient health based on product quality faults; product supply disruption to patients; GMP as well as regulatory obedience risks; multisite risks; multiproduct risks; fresh facility as well as alters to existing facility, for instance, start-ups, new commercial manufacturing processes, technology transfers as well as product termination.

After completion of the risk evaluation as well as risk control activities the outcomes must be summarized and communicated. The results may be documented in a new or existing report or they may be included as part of another document approved by appropriate decision-makers (e.g. site or functional management, system owner, quality unit, etc.). A risk review is vital if fresh risks or alterations to current risk levels are recognized through planned or unplanned incidents for example, routine operation, alterations, objections, product returns, discrepancies/deviations, data supervising, trends, inspections/audits, changes in regulatory environment, etc. Risk review may also include evaluation of, e.g.:

Efficacy of risk control activities and actions;

Changes in observed risk levels or existing controls.

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In principal there are two focuses when implementing QRM in commercial manufacturing: a system focus and a product focus.

CLASS IDENTIFICATION IN QRM

The outcome of a risk assessment may be a combination of quantitative and qualitative estimation of risk. As share of FMEA, a risk score or – Risk Prioritization Number (RPN) may be allotted to the divergence or to the time of the process that is influenced; this benefits to classify the deviation. RPN is computed by product of Probability (P), Detectability (D) and Severity (S), which are separately classified and scored. The Risk Priority Number (RPN) methodology is a method for examining the risk related with probable problems recognized during a Failure Mode and Effects Analysis (FMEA). Overview of Risk Priority Numbers - An FMEA can be functioned to recognize the probable failure modes for a product or procedure. The RPN technique then needs the analysis team to utilize previous experience as well as engineering decisions to rate every potential problem conferring to three rating scales:

- Severity, which rates the severity or harshness of the probable influence of the failure.
- Occurrence, which evaluates the likelihood that the failure will happen.
- Detection, which evaluates the likelihood that the challenge or problem will be discovered before it touches the end-user/customer.

Rating scales generally varies from 1 to 5 or else from 1 to 10, with the greater number signifying the greater seriousness or risk. For instance, on a ten point Occurrence scale, 10 specify that the failure is very probable to happen and is poorer than 1, which shows that the failure is very doubtful to happen. The precise rating descriptions as well as criteria are defined by the organization or the analysis team to fit the products or processes that are being analyzed. As an example, table 2 depicts a generic five point scale for Severity.

Table 2: **Criteria of Risk and Failure**

Rating	Description	Criteria
1	Very Low or None	Minor nuisance.
2	Low or Minor	Product operable at reduced performance.
3	Moderate or Significant	Gradual performance degradation.
4	High	Loss of function.
5	Very High or Catastrophic	Safety-related catastrophic failures.

RPN = Severity x Occurrence x Detection

The RPN value for every probable problem can then be utilized to compete the issues recognized within the analysis. Naturally, if the RPN falls within a pre-determined span, corrective measure may be suggested or needed to decrease the risk (i.e., to decrease the possibility of occurrence, surge the possibility of earlier detection or, if possible, decrease the severity of the failure effect). When applying this risk assessment technique, it is always significant to recollect that RPN ratings are comparative to a particular analysis. Therefore, an RPN in one analysis is comparable to other RPNs in the similar analysis but it doesn't seem to be compared with RPNs in other analysis.

Revised RPNs and Percent Reduction in RPN

In some instances, it may be suitable to review the initial risk evaluation built on the supposition (or the fact) that the suggested actions are finished. This gives a signal of the efficacy of corrective actions as well as can also be utilized to assess the value to the organization of executing the FMEA. To compute reviewed RPNs, the analysis teams allots another set of Severity, Occurrence and Detection ratings for every issue (utilizing the same rating scales) and perform a product of the revised ratings to compute the revised RPNs. If both initial as well as revised RPNs are allotted, the percent decrease in RPN can also be computed as follows:

$$\% \, Reduction \, in \, RPN = \frac{RPN_i - RPN_r}{RPN_i}$$

The initial ratings for a probable problem are S = 7, O = 8 and D = 5 and the revised/reviewed ratings are S = 7, O = 6 and D = 4, then the percent decrease in RPN from initial to revised is 40%. This shows that the organization has been capable to decrease the risk related with the issue by 40% through the implementation of the FMEA and the corrective actions.

Table 3 Initial Values

Failure		O	D	S	RPN
Medicines (Pharmaceuticals)	Problem	9	4	8	288

The revised reading after applying reduction in RPN are given in the below table. In the above table, first calculated readings are given.

Table 4 Final Values

Failure		O	D	S	RPN
Medicines (Pharmaceuticals)	Problem	7	4	7	196

Calculation of risk priority number (RPN)

RPN is calculated by multiplication of O, D and S values. RPN shows the relative importance of failure causes. The resulting rank of RPN values help the decision makers to decide which cause should be improved first. The highest the RPN value means the first rate.

Table 5 Comparison

	Severity	Detection	Occurrence	RPN
Initial	8	4	9	288
Revised	7	4	7	196
% Reduction in RPN				31.95%

Occurrence/Severity Matrix : Because the RPN is the multiplication of three ratings, dissimilar situations can produce alike or identical RPNs. For instance, an RPN of 100 can happen when S = 5, O = 5 and D = 4; when S = 1, O = 10 and D = 10; when S = 4, O = 5 and D = 5, etc. In addition, it may not be suitable to provide equal weight to the three ratings that include the RPN. For instance, an organization may count issues with great severity and/or great occurrence ratings to signify a higher risk than issues with high detection ratings. Therefore, founding decisions merely on the RPN (measured in isolation) may effect in ineffectiveness and/or improved risk. The Occurrence/Severity matrix gives an additional or substitute way to utilize the rating scales to prioritize probable problems. This matrix presents the occurrence scale vertically as well as the Severity scale horizontally. The points denote potential causes of failure as well as they are indicated at the location where the Severity and Occurrence ratings cross. The analysis team can then determine boundaries on the matrix to recognize high, medium as well as minimal priorities.

Rank Issues by Severity, Occurrence or Detection: Ranking issues conferring to their distinct Severity, Occurrence or Detection ratings is alternative path to analyze potential problems. For instance, the organization may regulate that corrective action is needed for any matter along with an RPN that comes under a specified range and also for any matter with a great severity rating. In this situation, a potential problem may have an RPN of 40 (Severity = 10, Occurrence = 2 and Detection = 2). This may not be great enough to activate corrective action built on RPN but the analysis team may choose to begin a corrective action at any case because of the incredibly high severity of the potential influence of the failure.

Risk Ranking Tables

Adding to, or instead of, the further risk evaluation tools defined here, the organization may decide to develop risk ranking tables to support the decision-making process. These tables will normally recognize whether remedial action is needed based on some product of Severity, Occurrence, Detection or RPN values.

O/S	1	2	3	4	5	6	7	8	9	10
1	N	N	N	N	N	N	N	N	C	C
2	N	N	N	N	N	N	10	8	C	C
3	N	N	N	N	10	7	6	5	C	C
4	N	N	N	8	6	5	4	4	C	C
5	N	N	10	6	5	4	3	3	C	C
6	N	N	7	5	4	3	3	2	C	C
7	N	10	6	4	3	3	2	2	C	C
8	N	8	5	4	3	2	2	2	C	C
9	N	7	5	3	3	2	2	1	C	C
10	N	6	4	3	2	2	1	1	C	C

Fig. 2 Sample risk ranking table

The letters and numbers inside the table indicate whether a corrective action is required for each case.

- N = No corrective action needed.
- C = Corrective action needed.
- # = Corrective action needed if the Detection rating is equal to or greater than the given number.

For instance, conferring to the risk ranking table in Figure 2, if Severity = 6 and Occurrence = 5, then corrective measure is needed if Detection = 4 or greater. If Severity = 9 or 10, then corrective measure is forever needed. If Occurrence = 1 and Severity = 8 or lower, then corrective measure is never ever needed, and so on.

Other variations of this decision-making table are possible and the appropriate table will be determined by the organization or analysis team

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based on the characteristics of the product or process being analyzed and other organizational factors, such as budget, customer requirements, applicable legal regulations, etc.

Higher Level RPNs

Finally, it may be wanted to allot RPNs at greater levels in the analysis built on the RPNs computed for the sources of failure. For instance, item RPNs might be beneficial in a manner to compare components to govern priority for corrective measure or to establish which component would be picked for addition in the design. The greater level RPN can be computed by finding the sum of all RPNs for all related sources of failure. For instance, to compute the Item RPN, it is needed to compute the RPNs for each cause related with the item as well as then to gain the sum of those RPNs, which is shown:

$$RPN_{item} = RPN_{cause1} + RPN_{cause}$$

RESULT

In this work, the focus was kept on solving by FMEA and improvement process of the Risk Priority Number (RPN). These numbers tells the risk of failure at a certain place in manufacturing line. Also these numbers are then ranked risk wise. Risk has been calculated by multiplying the severity, occurrence and detection. This because of improvement has been reduced hugely by 31.95%. Initial values were obtained as S=8, D=4, O=9 and after reduction, values were obtained as S=7, D=4, O=7. These values give the required result that was obtained during process. Failure mode analyses are done with the help of FMEA, RPN and Reduction of RPN method.

CONCLUSIONS

Failure mode assessment involves the FMEA tool and associated with it, risk management on a large basis. The risk management scheme comprises of four major components: risk assessment, risk control, risk review, and risk communication. These all of the four components are important. All the above methods should address the mentioned four basic components. FMEA is the desirable technique for risk management in the pharmaceutical industry as FMEA analysis comprise of greater reliability, improved quality, amplified safety as well as its involvement towards cost saving comprises of reduced development time as well as decreased waste and non value added operations. Initial values were obtained as S=8, D=4, O=9 and after reduction, values were obtained as S=7, D=4, O=7. These values give the required result that was obtained during process.

REFERENCES

[1] A. Kumar (2011). “FMEA: Methodology, Design and Implementation in a Foundry,” Int. J. Eng. Sci. Technol., vol. 3, no. 6, pp. 5288–5297.

[2] N. Banduka, I. Veža, and B. Bilić (2016). “An integrated lean approach to Process Failure Mode and Effect Analysis (PFMEA): A case study from automotive industry,” Adv. Prod. Eng. Manag., vol. 11, no. 4, pp. 355–365.

[3] H. C. Liu, J. X. You, P. Li, and Q. Su (2016). “Failure Mode and Effect Analysis under Uncertainty: An Integrated Multiple Criteria Decision Making Approach,” IEEE Trans. Reliab., vol. 65, no. 3, pp. 1380–1392.

[4] H. Soewardi and S. A. Wulandari (2019). “Analysis of Machine Maintenance Processes by using FMEA Method in the Sugar Industry,” IOP Conf. Ser. Mater. Sci. Eng., Vol. 528, No. 1.

[5] A. K. Josiah, J. N. Keraita, and P. N. Muchiri (2018). “Failure Mode Identification And Prioritization Using FMEA- A Case Study Of Corn Milling Industry,” vol. 15, no. 2, pp. 21–28.

[6] K. Baynal, T. Sari, and B. Akpinar (2018). “Risk management in automotive manufacturing process based on FMEA and grey relational analysis: A case study,” Adv. Prod. Eng. Manag., vol. 13, no. 1, pp. 69–80.

[7] J. Doshi and D. Desai (2017). “Application of failure mode & effect analysis (FMEA) for continuous quality improvement - multiple case studies in automobile SMEs,” Int. J. Qual. Res., vol. 11, no. 2, pp. 345–360.

[8] T. L. Nguyen, M. H. Shu, and B. M. Hsu (2016). “Extended FMEA for sustainable manufacturing: An empirical study in the non-woven fabrics industry,” Sustain., Vol. 8, No. 9.

[9] S. S. Pawar and W. S. Rathod (2016). “Process FMEA Analysis for Reducing Breakdowns of Mixed Model Assembly Line in Automobile Industry,” Int. J. Sci. Res., vol. 5, no. 4, pp. 1028–1032.

[10] R. R. Shinde, R. Shrivastava, and R. B. Morey (2015). “Failure Mode Effect Analysis-Case Study for Bush Manufacturing process,” Int. J. Sci. Eng. Appl. Sci., no. 1, pp. 2395–3470.

[11] Y. M. Degu and R. S. Moorthy (2014). “Implementation of Machinery Failure

Mode and Effect Analysis in Amhara Pipe Factory PLC, Bahir Dar, Ethiopia," Am. J. Eng. Res., vol. 03, no. 01, pp. 57–63.

[12] S. Ozilgen (2012). "Failure Mode and Effect Analysis (FMEA) for confectionery manufacturing in developing countries: Turkish delight production as a case study," Food Sci. Technol., vol. 32, no. 3, pp. 505–514.

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