An Assessment of Failure Modes and Criticality Analysis in a Pharmaceutical Industry by RPN Method

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Abstract

Pharmaceutical industry is one of the most rising industries in Bangladesh where various types of medicines are administrated to people with a view to curing them. Many workers as well as top and middle management are responsible to run the industry successfully. But because of not taking proper precautions, different failure causes result in various failure modes in each section of the industry that may affect the safety issue of the workers and effectiveness of the industry. In this research work, failure caused and failure modes were determined through performing a survey. Risk priority number method was evaluated for each failure modes caused by subsequent reasons of failures by learning the severity, detection and occurrence of each failure form. The higher risk priority number resulted in the greater criticality caused by failure modes. Proper preventive methods were encouraged to carry out to mitigate the criticality and to ensure proper working environment for all the workers involved in the pharmaceutical industry.

Keywords
Pharmaceutical, Criticality, Work environment, Failure modes, Risk priority number

1.0 Introduction
Pharmaceutical sector is one of the most growing sectors in Bangladesh. After the introduction of drug control ordinance in 1982, the condition of pharmaceutical industries of Bangladesh advanced a lot (Reich, 1994).Currently, 97% of lifesaving products are manufactured in local pharmaceutical companies. Though top pharmaceutical industries of Bangladesh, at the current time, are facing a golden age, many local pharmaceutical industries are facing barriers due to lack of technical skills in identifying and managing risks and failures. This research work is mainly based on a survey conducting in a local pharmaceutical industry with an aim of identifying, prioritizing and managing failures and risks occurred in the industry. Failure Modes Effects and Criticality Analysis (FMECA) is an established and widely used tool to identify, prioritize and manage failure modes occurring in different processes and businesses. FMECA is an efficacious technique for ranking potential failure modes on the basis of RPN (Risk Priority Number) which is a product of severity, occurrence probability and likelihood of detection. Failure modes having higher RPNs are considered to have a higher risk than those holding lower RPNs.

1.1 Objectives
The main purposes of the research work are to determine failure causes and failure modes in a pharmaceutical industry as well as to evaluate the criticality of the failure modes by establishing or utilizing risk priority number method.

2.0 Literature Review
Many researches have been conducted focusing on both failure modes effects and criticality analysis and RPN prioritization for assessing failure modes and risks. In one research, the risk priority number (RPN) methodology, an integral part of FMECA technique, was used for prioritizing different failure modes (Bowles, 2004). This research illustrated a detailed methodology for assessing RPN in a FMECA technique.
In another research, a new SAE FAMECA standard was introduced through three major changes for the improvement and advancement of FMECA technique with an aim of bringing FMECA technique into modern design practices. (Bowles, 1998). Another research was carried out to restore the fruitfulness of failure mode and effects analysis (FMEA) (Palady et al., 1994). This research totally focused on the advancement and enhancement of

FMEA through the introduction of four new developments named FMEA input form, area chart, screening matrix and cause summary sheet.
Moreover, a research provided a detailed guidelines on how to manage risk in production sector through a combined approach of preparing risk evaluation worksheet on the basis of plausibility and extremity as well as determining risk priority number (RPN) on the basis of eventuality, extremity and detection (Hridoy and Mohsin, 2020). Again, risk priority number (RPN) approach was used to assess hazards and risks in the sewing area of a readymade Garment industry in Bangladesh (Talapatra and Mohsin, 2020).
In a research article, FMEA was considered as a beneficial, productive and well-structured program in eliminating failure, mitigating failure effects and developing compensating provisions for failure occurrence (Bowles, 2014).In another research article, an intelligent FMEA (failure mode and effects analysis) system was formed with the help of back-progation neural networks (BPNs) with an aim of preventing failures took place in the operating periods of a system (Ku et al., 2008). Again, one research showed how risk matrix can be developed from the comparison of risk priority numbers (RPNs) and risk priority code (RPC) as well as can be used to assess and prioritize the risks of failure modes of a countermeasure using the qualitative information (Ashraf, 2015).
Before assessing failure modes, a detailed investigation in the operation area is mandatory. A research conducted in the shipbuilding industry of Turkey suggested close and precise investigation of all processes, accidents and wastes before assessing risks (Celebi et al., 2010).One researcher described both design FMEA and process FMEA techniques and how these techniques can be applied in the areas of design processes, manufacturing processes and assembly processes (Mode, 2002).
A detailed analysis and description was carried out on how to obtain safe, reliable and economical products as well as processes through failure mode and effects analysis (Carlson, 2012). This research provided a clear and efficacious guidelines as well as directions for conducting effective FMEAs. For the advancement and improvement of traditional FMEA technique, one research introduced both major shortcomings and deployment strategies to overcome the shortcomings and limitations (Kmenta and Ishii, 2000). In this research, it was suggested to conduct the FMEA around failure scenarios instead of failure modes as well as to evaluate risk using probability and cost. Further, the same researchers in their later published article urged and encouraged to conduct FMEA on the basis of failure scenarios as well as to take probability and cost into consideration for a consistent risk analysis (Kmenta and Ishii, 2004).
Furthermore, to enable FMEA technique for assessing multiple failures rather than single failure, one research proposed to integrate FMEA (failure mode and effects analysis) method with FTA (fault tree analysis) method (Pickard et al., 2005).

3.0 Methodology
To evaluate risk priority number, an interview was done among the workers of various experiences, ages, ranks and education of a pharmaceutical industry. Discussions in groups were also arranged among the participants

3.1 Sample Population and Data Collection
About 80 workers including senior manager, cleaners, section in charge, operators were the participants during the survey. Frequent hazards that they face often were found out during the interview session. Frequency of hazards (weekly, monthly, quarterly or yearly), detention, severity were evaluated using a scale. Results and suggestions were provided later.
Various Elements of Risk Priority number (RPN): Severity, Occurrence and Detention are three major components of RPN.

Severity:
Severity is considered as the effect or seriousness of a failure mode that may occur in a system. Poor appearance, erratic operations, noise, unstableness, impaired control in an operation are the frequent mode of failure in an event. Table 1 shows the criteria for evaluation of severity that is used to classified failure mode (Hridoy and Mohsin, 2020).

Table 1: Criteria Assessment for Severity of Effects

Ranking	Effects	Severity of the Effects
10	Precarious without warning	When a potential failure mode occurs and affects an operation, ranking of severity is very much higher and involves violation of government law without any

		warning.
9	Precarious with warning	When a potential failure mode occurs and affects an operation, ranking of severity is very much higher and involves violation of government law with warning.
8	Extremely High	Item becomes inoperable and primary function loses.
7	High	Item becomes operable. Customer dissatisfies with lower level of performance.
6	Medium	Item becomes operable. Comfort items are inoperable and experience of the customers is dissatisfactory
5	Lower	Item becomes operable. Comfort items are operable and experience of the customers is dissatisfactory
4	Very Low	Flaws are found in finishing. Items do not conform to the desired specification and most of the customers notice the flaws
3	Slight	Flaws are found in finishing. Items do not conform to the desired specification and average customers notice the flaws
2	Very Slight	Flaws are found in finishing. Items do not conform to the desired specification and biased customers notice the flaws
1	None	No effects are found

Occurrence: Occurrence is the likelihood of a failure mode to take place during an operation. Incorrect specification, insufficient capability of lubricants, inadequate instruction on maintenance, fatigue and instability of material, over stressing etc. are the frequent occurrences on failure modes. Table 2 shows the rankings of the failure mode occurrence (Celebi et al., 2010).

Table 2: Criteria Assessment for Occurrence of Failures

Ranking	**Possibility of Failure**	**Failure Rate**
10	Extremely High (Failure is almost unavoidable)	Greater than or equal to one out of two (≥0.5)
9		One out of three (0.33)
8	High (Failure is repeated frequently)	One out of eight (0.125)
7		One out of twenty (0.05)
6	Medium (Failure occurs occasionally)	One out of eighty (0.0125)
5		One out of four hundred (0.0025)
4		One out of two thousand (0.0005)
3	Slight (Comparatively few failures occur)	One out of fifteen thousand (0.0000667)
2		One out of one lakh and fifty thousand (0.00000667)
1	Remote (Failure is not likely to occur frequently)	Less than or equal to fifteen lakh (≤0.000000667)

Detection: Failure modes and causes are detected through the detection rate. It helps a company to analyze whether the failure cause will result in failure mode by the design program for verification established by the company. Table 3 shows criteria evaluation for detection rate ranking (Talapatra and Mohsin, 2020).

Table 3: Criteria Assessment for Ranking of Detection Rate

Ranking	**Detection of Failure**	**Possibility of Detection of Failure Mode**
10	Almost Unreliable	Failure cause and failure mode cannot be detected be design control method

9	Extremely Remote	Extremely remote possibility that failure mode and failure cause can be detected by the design control mechanism
8	Remote	Remote possibility that failure mode and failure cause can be detected by the design control mechanism
7	Extremely Low	Very lower possibility that failure mode and failure cause can be detected by the design control mechanism
6	Slight	Slight or low possibility that failure mode and failure cause can be detected by the design control mechanism
5	Medium	Medium possibility that failure mode and failure cause can be detected by the design control mechanism
4	Moderately High	Moderately high possibility that failure mode and failure cause can be detected by the design control mechanism
3	High	Higher possibility that failure mode and failure cause can be detected by the design control mechanism
2	Extremely High	Very high probability that failure mode and failure cause can be detected by the design control mechanism
1	Almost Reliable	Failure mode and failure cause almost certainly can be detected by the design control mechanism

Failure Causes and Relative Failure Modes: In a pharmaceutical industry following failure caused and subsequent failure modes were evaluated. Table 4 shows the failure causes and modes in the industry.

Table 4: Failure Causes and Failure Mode Analysis

Serial	Failure Causes	Failure Modes
1	Deficient working condition	1.Mental Dissatisfaction 2.Long term bad impact on physical well being 3.Slip from floor 4.Suffocation
2	Health Hazard	1.Dust and noise subjection 2.Subjected to ultraviolet radiation 3.Formaldehyde exposure 4.Constant tedious motion disorders 5.Allergic reaction 6.Fungal infections 7.Toxic effect on body 8.Deficiency of vitamins

3	Chemical Hazards	1.Irritants 2.Severeburn 3.Destruction of living tissue
4	Exposure to Heavy Metal	1.Breathing vapors 2.Dental Amalgam
5	Repetitive Motion and Wrong Posture	1.Musculoskeletal disorders 2.Spine problem 3.Tissue trauma 4.Back injury
6	Mechanical Hazards	1.Lack of focus towards work 2.Permanent disability
7	Insufficient Ventilation	1.Eyesight difficulty 2.Blurred Vision
8	Electric Hazard	1.Short circuits 2.Arc and spark 3.Catastrophy
9	Fire hazard	1.Burn 2.Death

4.0 Results and Discussion

Criticality Analysis by RPN Method: Risk priority number can be evaluated to find out the criticality of the failure modes that occur because of failure causes. If the RPN is high than the criticality for the failure cause is high. If RPN is low then it can be said that the particular failure mode cannot cause much harm to the workers (Celebi et al., 2010). Table 5 shows the RPN for individual failure mode.

Table 5: Risk Priority Number Analysis

Serial	Failure Causes	Failure Modes	Severity (S)	Occurrence (O)	Detection (D)	RPN= S*O*D
1	Deficient working condition	1.Mental Dissatisfaction	7	8	3	168
		2.Long term bad impact on physical well being	4	3	4	48
		3.Slip from floor	6	8	7	336
		4.Suffocation	6	7	4	164
2	Health Hazard	1.Dust and noise subjection	4	7	5	140
		2.Subjected to ultraviolet radiation	5	7	3	105
		3.Formaldehyde exposure	6	4	2	48
		4.Constant tedious motion disorders	6	8	6	288
		5.Allergic reaction	4	3	3	36
		6.Fungal infections	3	3	3	27
		7.Toxic effect on body	6	4	4	96
		8.Deficiency of vitamins	3	4	2	12
3	Chemical Hazards	1.Irritants	5	4	2	40
		2.Severeburn	8	6	8	384
		3.Destruction of living tissue	7	5	5	175

4	Exposure to Heavy Metal	1.Breathing vapors 2.Dental Amalgam	6 3	6 4	5 5	180 60
5	Repetitive Motion and Wrong Posture	1.Musculoskeletal disorders 2.Spine problem 3.Tissue trauma 4.Back injury	5 4 5 5	8 6 6 7	6 6 5 7	240 144 150 245
6	Mechanical Hazards	1.Lack of focus towards work 2.Permanent disability	5 8	8 6	6 7	240 336
7	Insufficient Ventilation	1.Eyesight difficulty 2.Blurred Vision	5 4	5 5	6 5	150 100
8	Electric Hazard	1.Short circuits 2.Arc and spark 3.Catastrophe	7 4 8	4 5 2	5 6 4	140 120 64
9	Fire hazard	1.Burn 2.Death	5 10	6 1	7 6	210 60

According to (Bowles 2004), if the RPN value is greater than 64 then quality must be improved. In the pharmaceutical industry 30 failure modes were evaluated and the respective risk priority number was calculated from the data of occurrence, severity and detection from the survey performed before. Among the failure modes, 9 failure modes such as long term bad impact on physical well-being caused by poor work environment; Formaldehyde exposure, Allergic reaction, Fungal infections and Deficiency of vitamins caused by health hazard; irritants caused by chemical hazard; Dental Amalgam because of heavy metal exposure; Catastrophe and death caused by electric and fire hazard respectively are less serious. Other twenty one failure modes are critical and proper prevention must be taken for the sake of safety culture of the workers involved in the pharmaceutical industry.
Graphical analysis can be performed to differentiate the risk priority number of various failure modes. Figure 1 shows the comparison of RPN of thirty failure modes caused by nine failure reasons in the pharmaceutical industry.

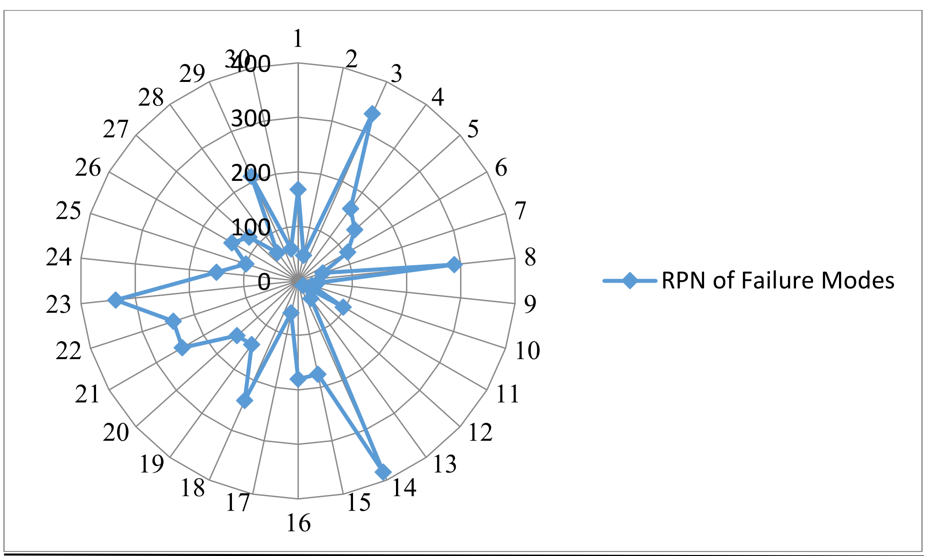

Figure 1: Comparison of risk priority numbers of failure modes

For ensuring safety of the workers effective methods have to be taken into account. Following preventive techniques can be considered in the pharmaceutical industry to reduce the criticality caused by failure caused and their subsequent failure modes:

- Proper use of personal protective equipment as well as first aid.
- Suitable arrangement of temperature control (AC, heater, fans etc.).
- Floors must be non-slippery and there should be enough space. In a word, upgrade of the working condition.
- Regular inspection of faculty and maintenance of discipline.
- Safety training and campaign must be arranged.

5.0 Conclusion

Workers spend most of the time in work place. If there are higher failure modes in the working environment, the efficiency as well as the safety of the workers are in stake. Failure modes and failure causes were evaluated in the research work. Also RPN method was prioritized to find out the major failure modes. Risk priority number played a vital role to find out the failure causes and failure modes. By analyzing criticality of the failure modes using risk priority number method, it was quite obvious that the chances of failures and risks are very high in a pharmaceutical industry. These may lead to various types of disorders and accidents. Overall it would have a negative impact on the safety culture for the industry. Future preventive methods have to be taken by the management for the safety purpose by making availability of the safety instruments as well as establishing discipline and training.

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