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Evaluation of Hazardous Scenarios and Risk Reduction Strategies in Chemical Industries Using HIRA and FMEA Techniques

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Abstract: *Exposure to chemicals represents a significant occupational health and safety (OHS) concern within chemical industry workplaces. Effective management of chemical hazards demands a coordinated approach involving occupational health and safety professionals, including general OHS practitioners, occupational hygienists, and occupational health specialists. This research focuses on the analysis of chemical hazards and the development of appropriate control measures in industrial environments. It examines how chemical toxicity is evaluated and how such evaluations are applied in regulatory and decision-making processes. The study begins with an overview of toxicological data availability and hazard identification, followed by discussions on risk assessment practices and occupational exposure limits. It further addresses key toxicological issues where scientific understanding remains incomplete, including historical perspectives on chemical reactivity and toxicity, acute and chronic exposure effects, chemical hazard classification systems, and methods for identifying, assessing, and controlling chemical risk. Preventing exposure to toxic substances is a critical priority, particularly at hazardous waste and chemical handling sites, where chemicals may exist in gaseous, liquid, or solid forms. These substances can enter the human body through inhalation, dermal absorption, ingestion, or injection via puncture wounds. Therefore, collaboration among a multidisciplinary team of occupational health and safety experts is essential to effectively prevent fatalities, injuries, occupational diseases, and long-term health impacts associated with chemical exposure.In this research, efforts are made to identify hazardous chemical scenarios and propose strategies to mitigate their adverse effects through systematic Hazard Identification and Risk Assessment (HIRA), Failure Mode and Effects Analysis etc.*

Keywords: Work place safety, Chemical laboratories, Hazards, Occupational safety, health analysis (OSH), Hazard Identification, Risk Assessment (HIRA), Failure Mode and Effective Analysis (FMEA), experimental approaches, Risk calculation, RPN Number calculation

I. INTRODUCTION

The chemical industry, encompassing industrial chemical production, inherently involves the use of substances that are hazardous, toxic, and potentially dangerous. The rapid growth and development of this sector amplify the risks associated with the handling, storage, and disposal of these chemicals. Many chemicals possess inherent hazards, including flammability, explosiveness, toxicity, and corrosiveness, which must be carefully managed throughout their entire lifecycle—from production to end-use. Effective risk assessment and management strategies are therefore critical to ensure the health and safety of personnel, the public, and the environment. Regulatory frameworks established by government authorities provide guidelines to mitigate these risks, but the dynamic nature of the chemical landscape—with markets evolving, mergers and acquisitions, and the introduction of new products—demands continual vigilance. In this context, project management, and particularly risk management in new product development, plays a pivotal role in balancing operational efficiency, safety, and competitive advantage. This study aims to analyze the risks inherent in

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chemical production, evaluate current safety regulations, and explore the role of proactive risk management practices in enhancing safety and supporting sustainable growth in the chemical industry. The regulation requires Employers to consult with employees in relation to:

1. Identification of major hazards and potential major accidents
2. Risk assessment
3. Adoption of control measures
4. Establishment and implementation of a safety management system
5. Development of the safety report

The active involvement of employees in identifying workplace hazards and implementing control measures significantly enhances their awareness of safety issues and is essential for achieving safe operational practices. To ensure compliance with regulatory requirements, chemical industries increasingly rely on specialized organizations such as Team Labs and workplace safety consultants to conduct comprehensive hazard analyses and risk assessments for their facilities. These assessments are complemented by the development of on-site emergency preparedness plans, in accordance with statutory acts and regulations. This collaborative approach not only strengthens regulatory compliance but also fosters a safety-conscious culture, enabling organizations to proactively manage risks and ensure the protection of personnel, the environment, and assets.

Fig. 1: Plant View [1]

Scope and Application of Study

This study provides a structured guide for the development and implementation of processes aimed at effectively integrating hazard identification and risk evaluation, with the ultimate goal of formulating strategies to minimize or manage risks prior to the commencement of work. The guide also offers practical approaches for:

• Identifying and responding to changing conditions that may influence hazard evaluation.
• Implementing hazard identification and risk assessment processes in institutions or laboratories not previously accustomed to these techniques.
• Assessing the effectiveness of implemented hazard identification and evaluation methodologies.

The guide has been prepared for researchers in chemical industries, with applicability at various stages of postgraduate research and industrial practice. Consideration has been given to the variable nature of research work in the preparation of this guide and in the presentation of the recommended techniques. Assessment approaches included are designed to be practical, straightforward, and adaptable for routine implementation. While the primary audience comprises research laboratories and their personnel, the guide may also provide valuable insights for other stakeholders in the chemical industry seeking to enhance workplace safety and compliance with regulatory standards.

Hazard Identification

The identification of hazards in the proposed study is of primary importance for the systematic analysis, quantification, and cost-effective control of accidents and process risks. A hazard is defined as a characteristic of a system or process that has the potential to cause an accident. Therefore, every component of the system must be thoroughly examined to evaluate its potential to initiate or propagate an unplanned event or a sequence of events that could lead to an accident.

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A comprehensive hazard identification process is essential to ensure that appropriate preventive and mitigative measures are implemented, thereby safeguarding personnel, equipment, and the surrounding environment.

S. No	Hazard Type	Examples
1	Agent	Carcinogenic, teratogenic, corrosive, pyrophoric, toxic, mutagenic, reproductive hazard, explosive, flammable, oxidizing, self-reactive or unstable, potentially explosive, reducing, water reactive, sensitizing, peroxide-forming, catalytic, chemical asphyxiant, non-ionizing radiation, biological/pathogenic hazard
2	Condition	High pressure, low pressure, electrical, uneven surfaces, pinch points, suspended weights, hot surfaces, extreme cold, steam, noise, cluttered workspace, magnetic fields, simple asphyxiants, oxygen-deficient spaces, ultraviolet radiation, laser light
3	Activity	Creation of secondary products, lifting, chemical mixing, long-term use of dry boxes, repetitive pipetting, scale-up operations, handling waste, transportation of hazardous materials, handling glassware and other sharp objects, heating chemicals, recrystallizations, extractions, centrifuging

Table 1: Examples of Hazards Commonly Identified for Research Activities [8]

Figure 1.2 Integration of Hazard Identification, Evaluation, and Control with the Scientific Method [6]

"Risk" has become a ubiquitous term in contemporary society, but is used in such a wide variety of contexts that its meaning has been blurred. The International Organization for Standardization (ISO) defines risk as "the effect of uncertainty on objectives." [11] Indeed, the world is riddled with uncertainty—a necessary byproduct of our inability to foretell the future. In the event the future could be precisely predicted, it could be controlled, rendering all types of endeavors successful.

Unfortunately, this is not the world we live in, nor the world in which businesses operate. As such, "all activities of an organization involve risk [12]. The mere existence of risk does not imply a foregone conclusion of failure, of course; risk can be both defined and calculated, allowing the exercise of some influence in the form of knowledge.2 The magnitude of risk is calculated as the combination of the probability of occurrence of harm and the severity of that harm, exhibited in a simple equation [13].

$$\text{Likelihood} \times \text{Severity} = \text{Risk}$$

This calculation captures the main concerns associated with risk—the chances that some undesirable event will occur, and how bad it might be if it does. The level of concern rises as egregious outcomes become increasingly likely, and subsides when consequences are less severe or rarer. In this way, the concept and calculation of risk reflects the general amount of apprehension with which we approach various activities.

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It follows that the management of risks is necessary to increase the probability that an identified goal will be achieved. For example, a thrill-seeking sky diver does not blindly launch him or herself out of an airplane; rather, specific safety controls are employed to ensure the jump will

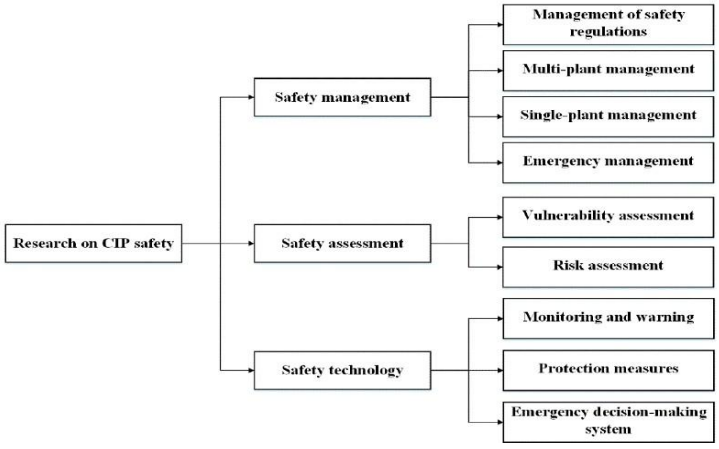
Objective of Study

Carryout a systematic, critical appraisal of all potential hazards involving personnel, plant, services and operation methods

1. Identify the existing safeguards available to control the risks due to the hazards.
2. Suggest additional control measures to reduce the risk to acceptable level.
3. Prepare a Risk register that will help in continuously monitoring these risks, detect any changes and ensure the controls are effective.

II. LITERATURE REVIEW

Tao Zeng et.al [17] the increasing demand for chemical products has driven the construction and development of chemical industrial areas, or so-called 'chemical industrial parks' (CIPs), but this has intrinsically raised the risk of major accidents. Therefore, it is significant and urgent to summarize the state of art and research needs in the field of CIP safety.



S. Fairhurst et.al [18] this paper is about industrial chemicals, the manner in which their toxicity is assessed and the use of such assessments in regulatory decision-making. It begins with general points concerning toxicological data availability and hazard identification, then moves on to risk assessment and occupational exposure limits, and finally looks briefly at three specific toxicological issues, asthma, chronic toxic encephalopathy, and ''low toxicity'' dust effects on the lung, where the science is far from resolved.

Igor Kozine et.al [19] the current paper gives an overview of the legislation and the methods used in safety and risk management in the chemical industry within Europe and in particular within the European Union. The paper is based on a report that has been written for the SOS I project under the Nordic nuclear safety research (NKS I. Safety- and risk-related matters in the process industry, in particular, in chemical, within the EU are subject to consideration at three levels: (1) EU legislation, 2) European/international standardization, and 3) socioeconomic analysis.

David J. Leggett et.al [20] the combination of hazard evaluation and risk analysis is an organized effort to pinpoint weaknesses in the design and operation of facilities that could lead to accidental or unintentional chemical releases, fires or explosions. These studies assist organizations with the goal of improving safety and managing the risk of operations.

Amol Paithankar et.al [21] for any industry to be successful it is to identify the Hazards to assess the associated risks and to bring the risks to tolerable level. Mining activity because of the very nature of the operation, complexity of the systems, procedures and methods always involves some amount of hazards.

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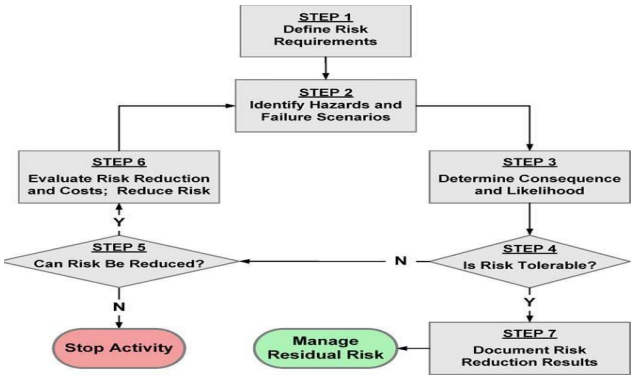

Literature gap

Previous studies have advanced understanding of chemical hazards and industrial safety management; however, critical gaps remain. While research has explored safety frameworks in chemical industrial parks [17], toxicological assessments [18,23], and legislative approaches [19], quantitative evaluation of exposure scenarios and practical implementation of risk controls is limited. Industrial and academic laboratories show higher accident rates due to insufficient systematic hazard analysis [20], and dynamic industries such as chemical face challenges from diverse chemical exposures and rapidly evolving processes [24–26].

Current hazard identification and risk assessment methods often rely on qualitative approaches, with limited integration of predictive tools like Failure Mode and Effects Analysis (FMEA). Moreover, unresolved toxicological issues, inconsistencies in regulatory application, and inadequate translation of hazard knowledge into worker-level safety practices highlight the need for a comprehensive, systematic approach.

This study addresses these gaps by combining Hazard Identification and Risk Assessment (HIRA) with FMEA to identify, evaluate, and mitigate chemical hazards in industrial workplaces

III. AREA OF STUDY

The Chemical Industries where the research work carried out is amongst India's TOP 300 companies 2024 in a Dun & Bradstreet listing In one of the most comprehensive and definitive rankings of India's leading, listed private and public sector company across several sectors compiled by Dun & Bradstreet, Industries features amongst the TOP 250 companies 2025! Industries was also conferred the Corporate Award for Outstanding Performance.

Fig. 2: Plant laboratory [27]

Company is global presence and experience in different markets allow the company to extend its expertise to clients in product technology, filings and much more. Today, plant is a globally preferred and reliable external manufacturing partner, leveraging its assets, expertise, and capabilities to deliver high-quality products. Specialized in contract research, development, and manufacturing and has strategic alliances with large chemical companies and MNCs.

Strong infrastructure including globally certified GMP compliant manufacturing facilities at six locations across India and an R&D center (Center of Excellence) in Goa for developing APIs as well as formulations meet global norms and stringent quality standards.

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Areas of expertise:

- Immediate-release dosage forms
- Extended-release dosage forms: matrix and pellets
- OROS technology
- Dry powder injections and syrups
- Novel drug delivery systems
- Technology transfer and documentation

IV. REQUIREMENT OF STUDY

Chemical manufacturing operations utilize physical processes, machinery and drug substances that present risks of fire, explosion, and injury or illness to people, plant and environment. These risks can only be properly managed by the application of thorough engineering analysis and mitigation of the hazards by knowledgeable and qualified professionals working as a team to review all aspects of the design of a new process. To do less invites an incident or disaster that can have serious financial effects on the company through interruption of manufacturing, destruction of physical plant and injury to people.

- Risk Assessment
- Risk identification
- Risk analysis
- Risk evaluation

It is the sharing of information about risk and risk management between the decision makers and others. The output/result of the quality risk management process should be appropriately communicated and documented. The included information might relate to the existence, nature, form, probability, severity, acceptability, control, treatment, detect ability or other aspects of risks to quality. The approach described can be used

- Thoroughly analyze products and processes to ensure the best scientific rationale is in place to improve the probability of success.
- Identify important knowledge gaps coupled with processes that need to be understood to properly identify risks.
- Provide a communication process that will best interface with all relevant parties involved in the Risk Management Plan.
- Make possible to transfer process knowledge and product development history.
- Enable the chemical industry to adopt a risk-based approach to development as described in external regulatory guidance.
- The Risk Management outputs will potentially very as reference documents to support product development and control strategy discussions in regulatory filings.

S. No	Risk management tool	Description/attributes	Potential applications
Basic Tools			
1 [34]	Diagram analysis, Flowchart, Check sheets, Process mapping, Cause/effect diagrams	Simple techniques that are commonly used to gather and organize data, structure RM processes and facilitate decision making	Compilation of observations, trends or other empirical information to support a variety of less complex deviations, complaints, defaults or other circumstances.
2 [35]	Risk ranking and filtering	Method to compare and rank risks Typically involves evaluation of multiple diverse quantitative and qualitative factors for each risk, and weighting factors and risk scores.	Prioritize operating areas or sites for audit/assessme nt, Useful for situations when the risks and underlying consequences are diverse and difficult to compare using a single tool.

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Advance Tools			
3 [36]	Fault tree analysis (FTA)	Method used to identify all root causes of an assumed failure or problem, Used to evaluate system or sub-system failures one at a time, but can combine multiple causes of failure by identifying causal chains, Relies heavily on full process understanding to identify causal factors	Investigate product complaints, Evaluate deviations
4 [37]	Hazard operability analysis (HAZOP)	Tool assumes that risk events are caused by deviations from the design and operating intentions Uses a systematic technique to help identify potential deviations from normal use or design intentions.	Access manufacturing processes, facilities and equipment, Commonly used to evaluate process safety hazards
5 [38]	Hazards analysis and critical control points (HACCP)	Identify and implement process controls that consistently and effectively prevent hazard conditions from occurring, Bottom-up approach that considers how to prevent hazards from occurring and/or propagating, Emphasizes strength of preventative controls rather than ability to detect, Assumes comprehensive understanding of the process and that critical process parameters (CPPs) have been defined prior to initiating the assessment. Tool ensures that CPPs will be met.	Better for preventative applications rather than reactive, Great precursor or complement to process validation, Assessment of the efficacy of CPPs and the ability to consistently execute them for any process
6 [39]	Failure modes effects analysis (FMEA)	Assesses potential failure modes for processes and the probable effect on outcomes and/or product performance,	Evaluate equipment and facilities; analyze a manufacturing process to identify high risk steps and/or

V. METHODOLOGY, CALCULATION AND RESULTS

The production of Bulk chemicals involves usage of many chemicals which are both hazardous and toxic in nature. The risks associated with the chemical industry are commensurate with their rapid growth and development. Apart from their utility, chemicals have their own inherent properties and hazards. Some of them can be flammable, explosive, toxic or corrosive etc. The whole lifecycle of a chemical should be considered when assessing its dangers and benefits. In order to ensure the health and safety of persons at or near the facilities, Government has approved some regulations. The regulation requires Employers to consult with employees in relation to: -

• Identification of major hazards and potential major accidents

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- Risk assessment
- Adoption of control measures
- Establishment and implementation of a safety management system
- Development of the safety report

The involvement of the employees in the identification of hazards and control measures enhances their awareness of these issues and is critical to the achievement of safe operation in practice. In order to comply with regulatory authorities, company Laboratories, have entrusted Team Labs and Consultants, hence to review and prepare Hazard analysis and Risk assessment for their facility along with an approach to on-site emergency preparedness plan as required under the acts and rules

Different steps involved in the risk assessment

1. Collect & organize the information

Gathering relevant information, reviewing appropriate references & identifying assumptions.
Tools can be used to categorize the information.
Define the limits of the RM exercise

2. Formulate the Risk Question

It is the starting point of the RM exercise, high level statement outlining the issue & purpose for conducting the RM exercise including risk factors, the scope of the issue and any related limits or constraints.

3. Choose Tool different tools include

Basic risk management facilitation methods (flowcharts, check sheets etc).
Failure Mode Effects Analysis and Failure Mode Effects and Criticality Analysis.
Fault Tree Analysis.
Hazard Analysis and Critical Control Points.
Hazard & Operability Analysis.
Preliminary Hazard Analysis.
Risk Ranking & Filtering.
Supporting statistical tools.

4. Identify Risks Factors and Related Hazards

A hazard is a failure that could cause potential harm to the patient. Once the hazards are recognized, they can then be categorized into one of five areas: Operator, Environment, System, Reagents, or Specimen.
These categories will make it easier to later identify types of controls necessary to reduce unwanted risk.

5. Define the Risk Components and scale [30]

$$Risk = PRIORITY \times DETECTABILITY \times SEVERITY$$

Where,
Severity : - Criticality of the product.
Priority : - Complexity of the site (multi-product). Detection : - Audit history.

6. Evaluate the risk for each hazard.

This is the step where you decide how often that a failure will occur.

7. Determine acceptability of risks

Once the risks are assigned, the next step is to look at severity and probability of harm to determine whether the risks are acceptable.

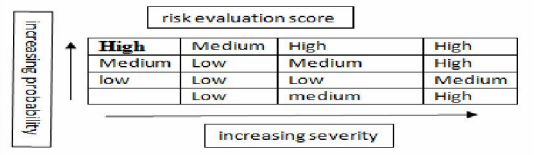

Figure 4.1 Risk Evaluation Score [31]

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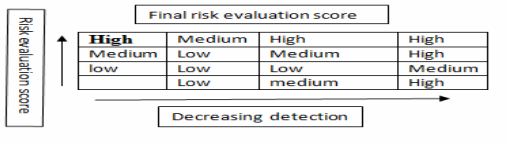

Figure 4.2 Final Risk Evaluation Score [32]

8. Determine Action Threshold

A level or value above which an action will take place and below which it will not.

9. Apply the tool

Analyze the detailed risks and quantify those risks using the scales for severity, probability and detection to provide a risk score.

Conclude what actions are required based on the threshold for action.

Result and calculations

However, failures of storage vessels and those during transportation have been reported more frequently than cases of plant failures. The failure rate of various equipment in a typical power plant is provided in the following table.

S. No	Failure rate	Failures 10-6/h
1	Electric motors (general)	10
2	Transformers (<15 kV)	0.6
3	(132-400k V)	0.7
4	Circuit breakers (general, <33k V)	2
5	(400kV)	10
6	Pressure vessels (general)	3
7	(High standard)	0.3
8	Pipes	0.2
9	Pipe joints	0.5
10	Ducts	1
11	Gaskets	0.5
12	Bellows	5
13	Diagrams (metal)	5
14	(Rubber)	8
15	Unions and junctions	0.4
16	Hoses (heavily stressed)	40
17	(Lightly stressed)	4
18	Ball bearings (heavy duty)	20
19	(Light duty)	10
20	Roll bearings	5
21	Sleeve bearings	5
22	Shafts (heavily stressed)	0.2
23	(Lightly stressed)	0.02
24	Relief valves leakage	2
25	Blockage	0.5
26	Hand- operated valves	15
27	Control valves	30
28	Ball valves	0.5
29	Solenoid valves	30
30	Rotating seals	7

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31	Sliding seals	3
32	'O'ring seals	0.2
33	Couplings	5
34	Belt drives	40
35	Spur gears	10
36	Helical gears	1
37	Friction clutches	3
38	Magnetic clutches	6
39	Fixed orifices	1
40	Variable orifices	5
41	Nozzle and flapper assemblies: Blockage	6
42	Breakage	0.2
43	Filters: blockage	1
44	Leakage	1
45	Rack-and-pinion assembles	2
46	Knife-edge fulcrum: wear	10
47	Springs (heavily stressed)	1
48	(Lightly stressed)	0.2
49	Hair springs	1
50	Calibration springs: creep	2
51	Breakage	0.2
52	Vibration mounts	9
53	Mechanical joints	0.2
54	Grub screws	0.5
55	Pins	15
56	Pivots	1
57	Nuts	0.02
58	Bolts	0.02
59	Boilers (all types)	1.1
60	Boilers feed pumps	2.5
61	Cranes	7.8

Table 3: Equipment Failure Rate

We have relied on the status of (FMEA) as a key tool in the identification, severity, impact and detection of risk. In this research, we found that it is best to use this tool to assess and determine the risks and the quality of the chemical industry because of the benefits of this method in calculation risks and severity. So the FMEA is implemented by defining the steps in a complex process and then determining the failure patterns for each step, according to use Ishikawa diagram, we therefore worked on the following steps:

Calculate by the following equation: RPN = (O × S × D)

O = the harmful event or hazard, the cause, the likelihood of occurrence of risk S = the severity of the effects of the event

D = the delectability of the cause of the event.

It identifies and evaluates these three risks the degree based on a 10-point scale for each risk, with (1) being lowest and (10) being highest. For the calculation of RPN, in this study we will adopt the following measures: O: - From (1-2) Very Low, (3-4) Low, (5-6) Moderate, (7-8) High, (9-10) Very High.

S: - From (1-2) Very Low, (3-4) Low, (5-6) Moderate, (7-8) High, (9-10) Very High.

D: - From (1-2) Very Low, (3-4) Low, (5-6) Moderate, (7-8) High, (9-10) Very High.

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Risk can also be expressed by the number and color code in the matrix which determines the level of risk in this study, as showed, the Green from 1 to 14 (the low risk area appears), the Yellow from 15 to 39 (the medium risk area appears) and the Red from 40 to 100 (the high risk area appears).

SEVERITY	OCCURENCE									
10	10	20	30	40	50	60	70	80	90	100
9	9	18	27	36	45	54	63	72	81	90
8	8	16	24	32	40	48	56	64	72	80
7	7	14	21	28	35	42	49	56	63	70
6	6	12	18	24	30	36	42	48	54	60
5	5	10	15	20	25	30	35	40	45	50
4	4	8	12	16	20	24	28	32	36	40
3	3	6	9	12	15	18	21	24	27	30
2	2	4	6	8	10	12	14	16	18	20
1	1	2	3	4	5	6	7	8	9	10

Fig. 5: Matrix of Risk

VI. CONCLUSION

According to the Failure Mode and Effective Analysis FMEA analysis, there is a high, medium and low risk in the production stages. The analysis revealed that a high risk of a red color in the preparation stage. It is a high risk, and it is not allowed. The medium risk of the yellow color was at the stage parting, coating and packaging, as for the stage of pressing, the risk was low and green color. Tables below presents an FMEA model for each of these stages, showing red, yellow and green areas showing the importance of intervention to carry out the treatments. The improvement procedure was identified by the experts. The improvement was oriented towards the elements of the process (worker, machine, material, manufacturing system, and management). The aim of the improvement was to improve quality by reducing risk.

Parting Stage:

Table 6.1 The FMEA analysis activity for parting stage

N	Potential Failure Modes	S	Potential Cause	O	Current Controls	D	RPN	Action Recommended	S	O	D	RPN
1	Little weight of active ingredients leads to in manufacturing process	10	Non Calibration	7	Proper	3	210	Continuous Training	10	5	3	150
			The weight is not real due to Humidity	5	Storage is not good	2	100	Improve the Environment for storage		4	2	80
			Vitalization of material because of ventilation devices	5	The speed of the air from the ventilators strong	4	200	Periodic Calibration		4	3	120
2	Mixing material leads to a similar table ineffective	10	There are no cards level handling on the container and the bag	7	Prepare	5	350	Continuous Training	10	6	4	240
					Factor control and inspection	4	280	Emphasis on Handling cards			4	240
					Store worker	3	210	Continuous Training			3	180
Total							1350					1010

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It determined two failures potential by the experts in the stage, which have potential effects on the effectiveness of the drug which means the level of quality is low, and the level of risk in was the yellow color which is a medium level, the degree of (RPN) it was equal (1350) degree out of index value, and after implementing the required improvement, the degree of (RPN) is dropped into (1010) degrees, in percent of improvement (74.8%). This means that the improvements dropped (340) degrees of RPN index.

Preparation stage:

In this they determine it by three cases of potential failure by the experts in production stage, those lead to high-quality risk. The degree of RPN was (2780) on the index scale, and this is the highest degree for risk calculated in these stage (the level of risk in this stage was the red color) this means that the risks are strong and UN acceptance. The cause of the high level of risk this stage resulted from critical stages in production of medicine and require special attention of employees and continuous follow-up of management, at implementing continuous improvement to variables in this stage, the degree of (RPN) dropped in to (1245) degrees with the percent of improving reached (44.7%). This means that (1535) degrees out of index value RPN dropped in this stage, which indicates the amount of improvement that has been achieved.

Table 6.2 The FMEA analysis activity for Preparation stage

N	Potential Failure Modes	S	Potential Cause	O	Current Controls	D	RPN	Action Recommended	S	O	D	RPN
1	High Humidity in Powder lead to adhesive part of the table in the form of bottoming	10	Increase the amount of water	7	Prepare	8	560	Continuous training	10	6	4	240
			Drying for a few Powder	6	Drying oven and drying agents	8	480	Periodic calibration		6	5	300
2	Powder in wet leads to Volatilization part of the article during the pressing	10	Increase drying time	7	Drying Worker	8	560	Continuous training	10	5	4	200
			Increase drying time	7	The drying agent record	4	280	Continuous training		6	3	180
			Lack of moisture during the milling	8	Drying Oven	5	400	Periodic calibration		4	5	200
3	Blending incomplete	9	Changes in the size of a grain of raw materials	7	It measures size but is unacceptable	8	504	Continuous training and the need to control worker	9	5	5	225
Total							2780					1245

Pressing stage:

At this stage, we identified four potential cases of failure, but it was with simple or weak risk, and their effect on product quality was low, where the degree of (RPN) before the improving reached (1293) and represented in the green color mount the levels of risks, though, This degree represents a certain level of risk and needs reduction to prevent occurrence in the operation, after making the required improvement, the degree of (RPN) dropped in to (1004) degree in the index value, with improvement percent reached (77.6%) this means that the amount of drop is (289).

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Table 6.3 The FMEA analysis activity for Pressing stage

N	Potential Failure Modes	S	Potential Cause	O	Current Controls	D	RPN	Action Recommended	S	O	D	RPN
1	High Humidity in Powder lead to adhesive of the part of the material in the mold	7	Drying for a few Powder	8	Bottoming Factor	1	56	Periodic calibration	7	7	1	49
			Increase pressure in the pressing device	5	Prepare	1	35	Continuous training		5	1	35
2	Increase the flow of powder leads to increase in the product size	10	10 non-support machine calibrated	5	A Visual inspection of the amount of the material	1	50	Seen need to factor control	10	5	1	50
3	Powder lack of flow leads to the small size of product	8	Little weight to the product leads to a small amount of the active ingredients	5	Machine operator and a visual inspection of the amount	2	80	Seen need to factor control	8	5	2	80
4	An increase in pressure leads to a very dense disk	10	Pressure is not correct to force	8	Operator entry and check	2	160	Continuous training	10	5	2	100
			Equipment malfunctio n	8	Fill depth	4	320	Calibration and maintenance		7	4	280
			Double powder flow	3	Visual Inspection	2	60	Monitor prior steps: Blending		3	2	60
5	Decrease in pressure leads to brittle and weak product	7	Pressure is not correct to force	8	Operator entry and check	4	224	Continuous training	7	6	3	126
			Equipment malfunctio n	8	Fill depth gauge annual calibration	4	224	Calibration and maintenance		5	4	140
			Double powder flow	3	Visual inspection	4	84	Monitor prior steps: Blending		3	4	84
Total							1293					1004

Coating stage:

At this stage, we identified five cases potential for failures, including medium and a low of risks, and that was with yellow and green color analyzing the causes of these risks, it is showed that management of a company depended on machines needing trained of skilled workers on how this machines work The direction of management is to depend on

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raw material with bad quality caused which raise the scale (RPN) which will reach (1644) degrees, and when the experts implement the issues of continuous improvement on this stage, the degree of (RPN)) dropped about (339) degrees to become (1305) degree, with the percent of improving reached (79.3%). The improvement that happened in this stage moved the level of risks from yellow to a green color.

Table 6.4 The FMEA analysis activity for Coating stage

N	Potential Failure Modes	S	Potential Cause	O	Current Controls	D	RPN	Action Recommended	S	O	D	RPN
1	Low temperature leads to product adhesion and deformation of the outer shape	7	The low temperatur e of device	5	Pan and factor pan	6	210	Calibration and training	7	5	5	175
2	High temperature leads to cohesion of the paste on product	9	High temperatur e in a siding	5	Pan and factor pan	6	270	Calibration and continuous training	9	5	4	180
3	A decrease in the materials quality leads to a colorful color is not required for the product	9	Origin is not good for colored material	3	Supplier	7	189	Evaluate supplied and manufacturer	9	3	5	135
					Manufact urer	5	135				5	135
4	Low percentage of polished material leads to emergence of non gloss in the product	5	Low proportion of material polished	3	Siding Factor	7	105	Continuous training	5	3	7	105
			Origin is good	3	Factor inspection	6	90			3	6	90
			Short time, rotation of the product in the polishing machine	6	Supplier material	5	150	Evaluate equipped		5	5	125
5	Not dry the product inside the oven siding leads to break the product in pan	9	The lack of a drying oven inside	5	Operator drying	4	180	Continuous training	9	4	4	144
					Siding and oven drying	7	315	Periodic calibration			6	216
Total							1644					1305

Packaging stage:

At this stage, there are three cases of failure should be paid that most were in yellow color, and this show the existence of medium risks, attention these cases have no effect on the health of the patient, but occurrence is high, this lead to the high degree of (RPN) that reached (1375). The review on the causes of this level of risk, shown that the employees do not have the responsibility of high attention they the importance of packaging of package operation, and its role in product quality, also not they complete the work of periodic maintenance of the machines, which leads to high risk in

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this stage. After continuous improvement and training for workers, the degree of (RPN) dropped into (688), so the amount of reduction is about (686) degrees from risks, and this shows that the percent of improvement was (50.1%).

We need in this study an international identification organization for both essential risks analysis and estimation as a helpful tool for improving products quality, risk evaluation face several challenges relates to practical application, including adapting new production processes, either included the essential framework relating human element and refuse or accept risks standards.

Table 6.5 The FMEA analysis activity for packing stage

N	Potential Failure Modes	S	Potential Cause	O	Current Controls	D	RPN	Action Recommended	S	O	D	RPN
1	The emergency of a shortage in the number of products inside Shift leads to unacceptable product	7	The presence of Powder during packaging	8	Operator packing	4	224	Continuous Training	7	5	4	140
			Increase product weight and size	7	Factor inspection	4	196			5	3	105
			Not to shift meal	7	Factor preparation	2	196	Worker control		6	2	84
2	Number not appear the meal and expiry date	9	Packaging machine is not good	7	Machine Operator	5	315	Periodic calibration	9	5	3	135
					Periodic maintenance of the machine	4	252				3	135
3	Shift derailment during packing	3	Packaging Machine	8	Operator packing	4	96	Continuous Training	3	5	3	45
					Periodic maintenance	4	96	Periodic calibration			3	45
Total							1375					689

Table 6.6 Total RPN for the Process

Process Step	RPN	Before Improvement			RPN	After Improvement		
		Green	Yellow	Red		Green	Yellow	Red
Parting	**1350**		×		**1010**		×	
Preparation	**2780**			×	**1245**		×	
Pressing	**1293**	×			**1004**	×		
Coating	**1644**		×		**1305**	×		
Packaging	**1375**		×		**689**	×		

We have investigated procedures of determination, analysis, measuring affecting the quality of the product, based on the steps and phases of quality risk management, and using some risk analysis and identification techniques, it provides both researchers and companies basic knowledge and correct practices to address risks, via reducing its impact along with facing it in future as also shown in the charts given by us in the study above.

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VII. FUTURE SCOPE AND RECOMMENDATIONS

a. Integration with Advanced Digital Tools: The implementation of FMEA/HIRA can be enhanced by integrating advanced digital technologies such as Artificial Intelligence (AI), Machine Learning (ML), and predictive analytics to identify potential failure modes more accurately and in real-time.

b. Automation and Real-Time Monitoring: Future studies can explore automated monitoring systems for critical process parameters, enabling dynamic risk assessment and immediate corrective actions, thereby further reducing the Risk Priority Number (RPN).

c. Broader Application Across Processes: The methodology can be extended beyond drug production to other chemical processes, including packaging, storage, and supply chain management, ensuring comprehensive risk mitigation across the product lifecycle.

d. International Standardization and Benchmarking: Aligning risk assessment practices with global standards (e.g., ICH Q9, ISO 31000) can improve consistency, regulatory compliance, and facilitate benchmarking with industry best practices.

e. Human Factors and Training Integration: Incorporating human factors analysis and focused employee training programs can further minimize risks associated with operational errors, enhancing overall product quality and patient safety.

Continuous Improvement and Knowledge Management: Establishing a dynamic risk knowledge repository can support continuous improvement by documenting lessons learned, best practices, and corrective actions for future process optimization.

VIII. RECOMMENDATIONS

1. Regular Risk Assessment: Conduct periodic FMEA/HIRA assessments across all stages of drug production to proactively identify new or evolving risks and ensure ongoing process reliability.
2. Strengthen Corrective Action Implementation: Ensure that identified corrective and preventive actions (CAPA) are effectively implemented, monitored, and verified to prevent recurrence of high-risk failures.
3. Employee Training and Awareness: Provide continuous training programs for production and quality teams to enhance understanding of risk management principles, hazard identification, and response strategies.
4. Adopt Digital Risk Management Tools: Utilize software-based risk assessment platforms for real-time monitoring, data analysis, and visualization of Risk Priority Numbers (RPNs) to support faster decision-making.
5. Align with International Standards: Incorporate global frameworks such as ICH Q9 and ISO 31000 to standardize risk management processes, ensuring compliance with regulatory requirements and industry best practices.
6. Continuous Improvement and Feedback Loop: Establish a systematic feedback mechanism to capture lessons learned from risk assessments, enabling continuous refinement of processes and sustained improvement in product quality.
7. Cross-Functional Collaboration: Encourage collaboration between quality, production, and regulatory teams to ensure comprehensive risk identification and mitigation across the entire production lifecycle.

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