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Research Article

Assessment of Quality Risk Management Systems in Pharmaceutical Manufacturers in Ethiopia: Cross-sectional Descriptive Study

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ABSTRACT

Effective quality risk management (QRM) is vital for informed decision-making and regulatory assurance; however, deficient systems often lead to suboptimal pharmaceutical products. This study assessed QRM implementation and effectiveness within Ethiopian Pharmaceutical Manufacturers (EPMs). A cross-sectional descriptive study was conducted among key personnel at six EPMs in Addis Ababa. Data were collected *via* self-administered questionnaires and analyzed using descriptive and inferential statistics in SPSS version 28. Findings revealed that while most EPMs have established risk frameworks, significant deficiencies persist in formal risk identification and quantitative assessment of likelihood and impact. A critical gap in regular staff training was also observed. Primary operational risks included raw material shortages, equipment malfunctions, and exchange rate fluctuations. Although foundational proficiency in identification and monitoring was noted, inconsistent formal application and underutilization of post-marketing systems, such as pharmacovigilance, remain problematic. To enhance compliance and safety, manufacturers should prioritize supply chain diversification, technological investment, and mandatory, ongoing QRM training programs.

Introduction

According to the pharmaceutical quality system (PQS) concepts, manufacturers are responsible for ensuring product safety and compliance through active senior management engagement and organization-wide dedication.[1,2] A cornerstone of this responsibility is effective quality risk management (QRM), a systematic process designed to facilitate informed decision-making and provide regulatory assurance by mitigating risks before they impact patient safety.[3,4] While the International Council for Harmonization (ICH) and the WHO advocate for science-based, formal QRM to foster innovation and regulatory flexibility, integrating these systems remains a complex and resource-intensive challenge.[5-7]

In Ethiopia, pharmaceutical manufacturers face significant risks to product quality and global competitiveness due to potential deficiencies in their risk management frameworks. Non-compliance often stems from inadequate adherence to current good manufacturing practices (cGMP) and a lack of comprehensive data regarding local risk identification and mitigation strategies. This study was developed to bridge this information gap, as understanding the specific operational and regulatory risks within the Ethiopian context is essential for improving local manufacturing standards. The purpose of this study is to assess the current level of QRM knowledge and the effectiveness of risk management practices among Ethiopian pharmaceutical manufacturers (EPM).

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By identifying common risks and existing procedural gaps, this research serves as a diagnostic tool to transform abstract quality goals into measurable actions, ultimately enhancing the safety and accessibility of locally manufactured medicines.

Literature Review

Concept of Risk Management Process

By adopting proactive QRM, manufacturers facilitate informed decision-making and provide regulators with assurance regarding their risk-mitigation capabilities. This systematic approach prioritizes reducing the likelihood of adverse events through the identification and documentation of probable causes and consequences, as preventing risks is more beneficial than addressing their effects post-occurrence.[3,4]

Selecting the right risk assessment tool is crucial, with no single best option. The choice depends on the analysis depth, risk complexity, and user familiarity. Basic assessments often use risk ranking & filtering or flowcharting. For advanced analysis, failure mode effect analysis is common. Combining tools like fault tree analysis (FTA) or fish-bone with hazards analysis and critical control point (HACCP) can enhance complex evaluations.[8]

Review of a Study Related to Risk Management Practice in Industry

The WHO promotes quality decisions and regulatory commitments based on a science-based understanding of processes and QRM, thereby fostering innovation and providing greater flexibility for manufacturers. This approach enhances transparency, data management practices, and data quality to guarantee adherence to GMP standards. [6]

A risk modeling framework for the pharmaceutical industry in the USA (2011) provides examples of its application in the pharmaceutical sector and explains how GMP guidelines, effective pharmaceutical regulation and inspection, and efficient manufacturing and distribution process management can all lower risks. Researchers are tasked with assessing compliance success in the pharmaceutical industry through risk modeling, offering a practical and focused perspective. [9] A study conducted by Laura Curran at the National College of Ireland in 2022 highlighted that risk management, analytical testing, and project management are crucial components of business development. These elements adhere to different standards and foster a cohesive approach that is influenced by company culture and individual attitudes towards risk. [10] Similarly, a study conducted in Indonesia by Kunthi R. *et al*. (2018) identified critical success factors such as organizational culture and structure, information technology infrastructure, top management support, and human resources support, which contribute to the effective implementation of a company's knowledge management practices. Notably, senior management support was shown to be the most crucial element in the knowledge management implementation process. [11]

Singh U. K. *et al*. look into the significance of QRM in pharmaceutical products and processes to ensure patient safety and dependable performance. This method lowers the hazards that patients face when receiving medication. Development study data can inform QRM procedures and assist in acknowledging that design naturally incorporates quality into the product. [12] Similarly, a study conducted by Ismael OA and Ahmed MI in 2020 employed QRM techniques, including brainstorming and fishbone analysis, to identify potential risks within a pharmaceutical plant in Iraq over 12 to 13 weeks period. The study revealed that pharmaceutical manufacturers face significant risks that impact patient safety and product quality, emphasizing the need for careful management to ensure patient safety and maintain product quality.[13] In addition to this, employing FMEA technology correctly has significantly boosted quality by minimizing flaws and potential hazards in manufacturing. Al-Hokamaa company has seen positive outcomes from using this method as part of their quality risk management strategies.[13]

A study conducted by Abda Zameerin in 2017 on the pharmaceutical business in the Boston area assessed respondents' knowledge and awareness regarding risk assessment and management techniques. The findings revealed the following: 58.33% of respondents did not believe they had reasonable expectations for their project work; 50% believed there were essential skills required for the project, but no one known to possess them; and 41.67% cited a lack of necessary tools.[14] Similarly, a defect and root cause analysis conducted in East Africa in 2018 and 2019 examined the causes of online damage to acaricide labeling. The study found a loss of 1.01% of labels during the study period, after which Corrective and Preventive Actions (CAPA) were implemented. Following the application of these preventive and corrective measures, online damages to labels decreased.[15] Generally, there is limited information available regarding risk assessment systems for pharmaceutical manufacturing companies in Ethiopia.

Methods And Materials

This cross-sectional descriptive study, conducted from July 10 to August 12, 2024, utilized purposive sampling to select six representative large-scale pharmaceutical manufacturers in Addis Ababa, Ethiopia, based on their high production volumes and diverse dosage forms. Companies producing only medical supplies or operating on a small scale were excluded. Within these firms, five key technical and managerial personnel involved in quality assurance were purposively selected as respondents. The study investigated the implementation of risk management systems as the dependent variable, while independent

variables included employee training, workload, education level, work experience, and manufacturer profitability.

Data Collection Technique

Data were collected using a self-administered questionnaire featuring both structured and open-ended questions, which was pre-tested among six non-participant employees to ensure clarity and validity. Following modifications based on the pre-test, the final instrument was distributed to key personnel at the selected manufacturers. To maintain data integrity, all responses were double-checked for accuracy during the collection process. The data were then organized, coded, and analyzed using Microsoft Excel and SPSS version 28, with the methodology specifically aligned to the study's objective of assessing risk management practices within the pharmaceutical manufacturing sector.

Data Analysis

To characterize the data, descriptive statistics including frequencies, percentages, means, medians, and standard deviations were utilized. Qualitative information was transformed into quantitative data through systematic coding, categorization, and the application of Likert scales. To investigate associations between variables and determine the relationships between specific QRM activities, inferential techniques were employed, specifically the Fisher-Freeman-Halton exact test for cross-tabulation and Kendall's Tau-b for correlation analysis. All findings were subsequently organized into tables and graphs to illustrate variable characteristics, patterns, and trends.

Results

Evaluation of Risk Management Systems in the Pharmaceutical Industries

Self-administered questionnaires were distributed to 30 key respondents across six pharmaceutical companies ($n=30$). The participant profile included six quality assurance (QA) managers (20.0%), four general managers (13.3%), and four quality control (QC) managers (13.3%), while the remaining 16 respondents (53.4%) held various other technical or managerial positions. All participants possessed significant professional expertise, with a minimum of six years of experience in the pharmaceutical industry and at least one year in their current role. Educational qualifications were high: seven respondents (23.3%) held a Master of Science (MSc) degree—specifically five in pharmacy-related fields (16.7%) and two in chemistry (6.7%). Furthermore, 20 respondents (66.7%) held a Bachelor of Science (BSc) in Pharmacy, and three (10.0%) held a BSc in Chemistry. The demographic characteristics of the participants are summarized in Table 1.

Table 1: Demographic characteristics of respondents of pharmaceutical manufacturers (N=30)

Respondent's education levels	*Frequency*	*Percent*
M.Sc. in pharmacy	5	16.7
Bachelor of pharmacy degree	19	63.3
M.Sc. in chemistry related fields	2	6.7
Bachelor of Science in biology or chemistry	4	13.3
Respondent's department		
Production	19	63.3
Quality control	4	13.3
Quality assurance	6	20
Research and development	1	3.3
Respondents' roles in department		
General manager	4	13.3
QC manager	4	13.3
Production manager	1	3.3
QA manager	5	16.7
In process QA manager	1	3.3
Syrup and ointment division	1	3.3
Production division head	3	10
Technical manager	4	13.3
Quality assurance	6	20
Research and development	1	3.3
Respondent's total work experience		
6–10 years	8	26.7
>10 years	22	73.3
Respondent's current position work experience		
1–5 years	2	6.7
6–10 years	16	53.3
>10 years	12	40

Table 2 evaluates risk management practices using a 5-point Likert scale (1 = Very Poor to 5 = Very Good). Most practices received a positive evaluation, with median and mode values of 4.00, indicating generally good management as reported by participants. A notable exception was the alignment of management practices with regulatory standards, which had a mode of 3. Documentation of risk activities showed the highest variability (SD = 0.928), while assessments of risk likelihood and severity demonstrated the greatest consistency (SD = 0.691). Statistically, all items significantly differed from the neutral midpoint of 3 ($p < 0.001$), confirming a non-neutral perception of these practices.

Evaluation of Risk Management Systems in the Post-Marketing Phase

The implementation of the post-market surveillance systems, as reported by the respondents, is summarized

Table 2: Assessment of RMP in pharmaceutical manufacturers in Ethiopia, 2024(N = 30)

Items	*Mean*	*Med*	*Mod*	*SD*	*p-value*
Organization has a formalized risk management system in place for pharmaceutical manufacturing	3.90	4	4	0.759	<.001
Organization has a systematic process for identifying potential risks within the manufacturing process	4.03	4	4	0.718	<.001
We conduct thorough assessments to evaluate the severity and likelihood of identified risks	4.07	4	4	0.691	<.001
Our organization continuously monitors risks throughout the manufacturing process.	3.80	4	4	0.805	<.001
We maintain comprehensive documentation of risk management activities and report	3.97	4	4	0.928	<.001
Risk management practices are seamlessly integrated into our quality control processes.	3.93	4	4	0.785	<.001
Regularly review and improve RMP based on feedback and evolving industry standards.	3.77	4	4	0.858	<.001
RMP align with regulatory requirements	3.67	4	3	0.802	<.001
Adequate measures are in place to mitigate identified risks to an acceptable level.	3.97	4	4	0.765	<.001
Effective communication and collaboration among departments regarding risk management initiatives.	3.87	4	4	0.776	<.001

Note: RMP: Risk management practice

in Table 3. It includes the number and percentage of 'Yes' or 'No' answers, along with the corresponding *p-values*, which were tested at a significance level of 0.5 using the one-sample binomial test of proportions.

The implementation of post-market surveillance systems varied significantly across the surveyed manufacturers. While respondents reported near-universal adoption of product quality complaint systems and recall monitoring (96.6%), implementation rates for more specialized clinical and expert-driven systems were notably lower, specifically for post-market clinical studies (16.67%) and advisory committees (20.0%). Intermediate implementation levels were observed for other critical risk management tools: pharmacovigilance (60.0%), risk evaluation and mitigation strategies (53.3%), adverse event reporting systems (50.0%), and signal detection and analysis (40.0%).

Challenges in Implementing Effective Quality Risk Management System

Table 4 highlights significant challenges in risk management implementation among pharmaceutical manufacturers. While a majority of respondents reported difficulties in recognizing potential risks (60%), the capacity for quantitative risk assessment was even lower, with only 40% of manufacturers applying practices to evaluate risk probability and impact. Conversely, participants expressed high confidence in resource management and adaptability; 90% believed resource allocation was effective, and 73.3% felt capable of managing evolving challenges. A binomial test of one-sample proportions (test value = 0.5) confirmed that these positive perceptions were statistically significant for both adequate resource allocation (N = 27, $p < 0.001$) and the ability to keep pace with change (N = 22, $p = 0.018$).

Table 3: RMP systems and processes used by pharmaceutical companies in post marketing phase

Items	*Yes*	*No*	
	N (%)	*N (%)*	*p-value*
Adverse event reporting systems (AERS)	15 (50)	15 (50)	1
Pharmacovigilance systems	18 (60)	12 (40)	0.362
Signal detection and analysis	12 (40)	18 (60)	0.362
Risk evaluation and mitigation strategies (REMS)	16 (53.3)	14 (46.7)	0.856
Product quality complaint systems	29 (96.7)	1 (3.3)	<.001
Recall monitoring and communication	29 (96.7)	1 (3.3)	<.001
Post-market clinical studies	5 (16.7)	25 (83.3)	<.001
Advisory committees and expert panels	6 (20)	24 (80)	0.001

Frequently Observed Risks in Pharmaceutical Manufacturing

The pharmaceutical manufacturers reported a range of significant risks, as shown in Fig. 1. Among the regulatory challenges, the lengthy approval process was the most frequently observed risk, reported by 53.3% of respondents. Regarding supply chain risk, raw material shortage was reported by a high 80.0% of participants. Similarly, for operational risk, equipment failure was the most common issue, noted by 83.3% of respondents. From a financial risk perspective, exchange rate fluctuations

Table 4: Assessment of challenges in implementing an effective risk management system

Items	*Yes*	*No*	*sign 2- tailed*
	N (%)	*N (%)*	*p-value*
Recognizing all potential risks can be difficult	18 (60)	12 (40)	0.361
Assessing probability and impact	12 (40)	18 (60)	0.361
Adequately allocating resources	27 (90)	3 (10)	<.001
Keeping pace with change	22 (73.3)	8 (26.7)	0.018
Other (please specify)	-	-	

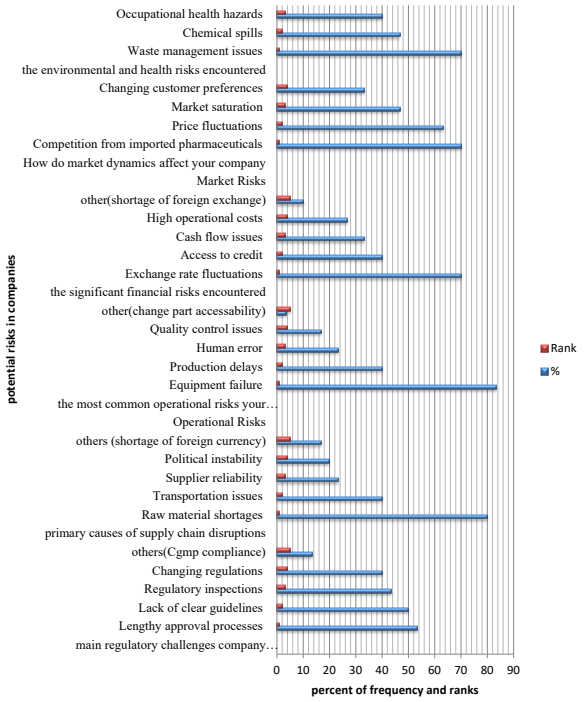

Fig. 1: Frequently Observed Risks in Pharmaceutical Companies in Ethiopia, 2024

represented the greatest risk, reported by 70.0% of respondents. Furthermore, concerning market risk, the manufacturers are largely affected by competition from imported pharmaceuticals, as reported by 70.0% of respondents. Finally, within environmental and health risks, waste management risk was also reported by 70.0% of respondents.

Level of Awareness, Attitude and Knowledge Regarding Risk Management

Awareness of risk management

Table 5 analyzes respondent perceptions of risk management using a 5-point Likert scale (1 = Very Poor to 5 = Very Good). While most respondents reported a foundational understanding of risk management—with 46.7% rating their familiarity as acceptable and 30.0% as good—only 13.3% claimed very good proficiency, and 10.0% reported poor knowledge. Perceptions of the importance of QRM for patient safety were generally positive (40.0% good), yet a combined 46.7% rated its importance as merely acceptable or poor. Awareness of regulatory requirements was notably inconsistent; although 36.7% reported good awareness, 23.3% rated their knowledge as poor or very poor, indicating a significant compliance gap. Conversely, organizational protocols were better received, with 60.0% rating their establishment as good. Regarding regular training, 46.67% rated the provision as acceptable, while 10.0% identified it as a weakness.

Knowledge of risk management practices

Table 6 summarizes employee knowledge of risk management practices on a 5-point scale (1 = Very Low to 5 = Very High). Respondents demonstrated high proficiency in corrective and preventive actions (CAPA) and documentation requirements, with 83.3% rating their knowledge as high or very high for both. Similarly, good manufacturing practices (GMP) knowledge was

Table 5: Level of awareness regarding the risk management system of pharmaceutical manufacturers in Ethiopia, 2024

Items	*1*	*2*	*3*	*4*	*5*
	N (%)	*N (%)*	*N (%)*	*N (%)*	*N (%)*
Employee familiar with the concept of risk management in pharmaceutical manufacturing.	-	3(10)	14(46.7)	9(30)	4(13.3)
Employees understand the importance of risk management in ensuring product quality and patient safety.	-	4(13.3)	10(33.4)	12(40)	4(13.3)
Employee aware of regulatory requirements related to risk management in pharmaceutical manufacturing.	3(10)	1(3.3)	8(26.7)	11(36.7)	7(23.3)
Organization has established protocols for risk management in pharmaceutical manufacturing.	-	-	10(33.3)	18(60)	2(6.7)
Employee receives regular training on risk management practices	-	3(10)	14(46.7)	5(16.7)	8(26.7)

Rating scale: 1 = very poor to 5 very good

Table 6: Knowledge of risk management practices in pharmaceutical manufacturers in Ethiopia, 2024 (N=30)

Items	*1*	*2*	*3*	*4*	*5*
	N (%)	*N (%)*	*N (%)*	*N (%)*	*N (%)*
Hazard analysis and critical control points (HACCP) principles	2 (6.7)	4 (13.3)	11 (36.7)	10 (33.3)	3 (10)
Failure mode and effects analysis (FMEA) methodology.	-	-	12 (40)	11 (36.7)	7 (23.3)
Good manufacturing practices (GMP) related to risk management.	-	-	6 (20)	13 (43.3)	11 (36.7)
Risk assessment techniques specific to pharmaceutical manufacturing.	-	3 (10)	8 (26.7)	6 (20)	13 (43.3)
Corrective and preventive actions (CAPA) in response to identified risks.	-	-	5 (16.7)	10 (33.3)	15 (50)
Documentation and reporting requirements for risk management activities	-	-	5 (16.7)	10 (33.3)	15 (50)

robust, with 80% reporting high or very high familiarity. Knowledge of specific risk assessment tools was more moderate: while 70% reported at least a moderate understanding of HACCP, 20% rated their knowledge as low or very low. For FMEA, 76.7% reported moderate to high knowledge, though none reached the "very high" tier. Despite 63.3% claiming high or very high expertise in general risk assessment techniques, a 36.7% gap in moderate-to-low proficiency persists, indicating a need for targeted training in systematic risk tools to supplement the strong foundational knowledge in GMP and CAPA.

Risk Identification Techniques used in Pharmaceutical Manufacturers

Table 7 details the frequency of risk identification techniques using a 5-point scale (1 = Never to 5 = Very Often). The Checklist method is the most prevalent, with 90% of respondents using it "Sometimes" or "Often," and zero reports of non-use. Root Cause Analysis (RCA) is also consistently applied, with 100% of participants utilizing it at least "Sometimes." FMEA and SWOT analysis show high but variable adoption; 93% of respondents utilize FMEA and 96.7% use SWOT with varying frequency. In contrast, Brainstorming and Scenario Analysis exhibit less consistency; while 53.4% use Brainstorming frequently, Scenario Analysis is the least utilized technique, with 23% of respondents rarely or never employing it.

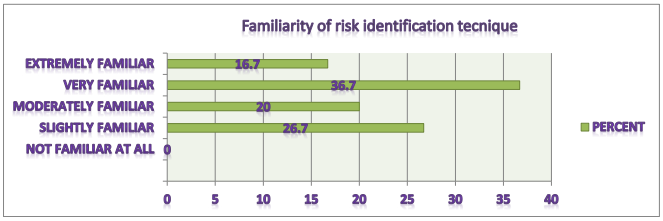

Fig. 2: Respondents' familiarity with risk identification techniques, 2024 (N = 30)

Fig. 2 shows the respondents' familiarity with a specific risk identification technique, based on a 5-point Likert scale. The responses indicate that the majority of participants (53.4%) are very familiar with the technique. However, a significant portion of the respondents reported lower levels of familiarity, with 20.0% being moderately familiar and 26.7% being slightly familiar.

Regarding the effectiveness of the risk identification technique, most respondents believed the technique to be moderately effective. About 43.3% considered it moderately effective, while 13.3% found it slightly effective. In addition, 30.0% rated it as very effective, showing that a significant portion recognized its impact, though its effectiveness might differ depending on the situation. Only a small portion (10.0%) rated it as extremely effective. Interestingly, none of the respondents

Table 7: Overall risk identification techniques used in pharmaceutical organization

Items	*1*	*2*	*3*	*4*	*5*
	N (%)	*N (%)*	*N (%)*	*N (%)*	*N (%)*
Brainstorming sessions	-	3 (10)	11 (36.7)	8 (26.7)	8 (26.7)
SWOT analysis (Strengths, Weaknesses, Opportunities, Threats):	1 (3.3)	6 (20)	10 (33.3)	5 (16.7)	8 (26.7)
Failure mode and effects analysis (FMEA)	1 (3.3)	1 (3.3)	16 (53.3)	5 (16.7)	7 (23.3)
Root cause analysis (RCA)	-	-	10 (33.3)	12 (40)	8 (26.7)
Scenario analysis	4 (13.3)	3 (10)	15 (50)	6 (20)	2 (6.7)
Checklist	-	1 (3.3)	10 (33.3)	17 (56.7)	2 (6.7)
Others	-				

It was rated by respondents as: 1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5= Very often

Table 8: Risk identification techniques effectiveness

Effectiveness	*Frequency*	*Percent*
Slightly effective	4	13.3
Moderately effective	14	46.7
Very effective	9	30.0
Extremely effective	3	10.0
Total	30	100.0

felt that the technique was ineffective. Table 8 provides more details on the effectiveness of these techniques.

Risk Mitigation Strategies used in Pharmaceutical Companies

Table 9 evaluates quality risk mitigation strategies using a 5-point Likert scale. Supplier diversification is the most established strategy, with 63.3% of respondents practicing it "Often." Dedication to employee training is also high, with 83.3% engaging in programs "Often" or "Very Often," though 16.7% reported "Rarely" training, indicating a need for greater consistency. Technological investment showed mixed application: while 63.3% utilize it frequently, 23.3% reported "Rarely" investing, which may impact long-term operational efficiency. Similarly, financial hedging—used to mitigate operational financial risks—exhibited moderate uptake, with 43.3% practicing it "Sometimes" and 36.7% "Often." Overall, while mitigation efforts are evident, the variability in technology and financial planning suggests pockets of vulnerability across the sector.

Fig. 3 shows how respondents view the effectiveness of risk mitigation strategies, divided into four levels. The results indicate varied opinions, with the majority (46.7%) rating the strategies as moderately effective. A significant portion of respondents rated the strategies positively, with 30.0% considering them very effective and 20.0% considering them extremely effective, emphasizing their essential role in managing risks. However, a small percentage (3.3%) assessed the strategies as slightly effective, suggesting that a few respondents view these strategies as somewhat lacking in impact.

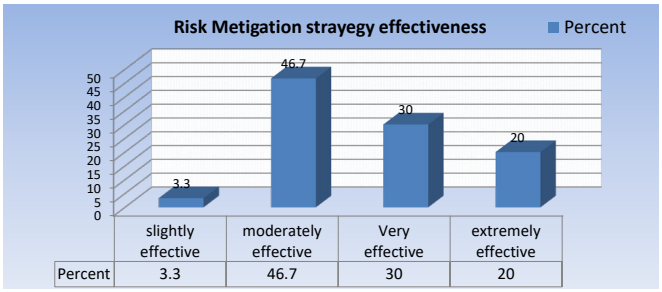

Fig. 3: Effectiveness of risk mitigation strategies for identified risks, 2024 (N = 30)

Relationship between Different QRM System Activities

As observed in Table 10, all the variables—risk identification techniques, risk management strategies, QRM system awareness, QRM system knowledge, and risk management practice (RMP)—are significantly and positively correlated with each other. This finding indicates that improvements in one area are likely to be associated with improvements in the others, particularly in relation to overall risk management processes. The strongest correlations are observed between strategies and knowledge, and between awareness and Knowledge, suggesting that focusing on enhancing organizational awareness and implementing robust strategies could significantly improve overall employee knowledge and subsequent risk management practices.

Table 11 outlines key operational trends concerning workload, government support, and training capacity across the six surveyed companies. Findings from personnel interviews revealed a diverse workload landscape: two manufacturers reported high-intensity environments with substantial task volumes and deadlines, while three maintained a balanced (medium) workload, and one reported low intensity. Government support was prevalent but not universal, with four companies benefiting primarily from tax-free raw material imports. Training depth also varied significantly; while four companies provided comprehensive "full training" programs, two offered only "partial training" limited to immediate job-related skills. These partial programs notably excluded critical broader competencies such as cGMP requirements, QRM systems, and ongoing quality monitoring, highlighting a potential vulnerability in those organizations' quality assurance frameworks.

Table 9: Quality risk mitigation strategy by pharmaceutical industries, 2024 (N = 30)

Strategies	*Never (1)*	*Rarely (2)*	*Sometimes (3)*	*Often (4)*	*Very often (5)*
	N (%)	*N (%)*	*N (%)*	*N (%)*	*N (%)*
Diversifying suppliers	1 (3.3)	2 (6.7)	8 (26.7)	19 (63.3)	-
Investing in technology	1 (3.3)	7 (23.3)	3 (10)	12 (40)	7 (23.3)
Employee training programs:	-	-	5 (16.7)	12 (40)	13 (43.3)
Financial hedging	1 (3.3)	3 (10)	13 (43.3)	11 (36.7)	2 (6.7)
Others	-				

Table 10: Correlation analysis of various activities in QRM systems in companies

Correlations analysis (Kendall's tau_b)		*Techniques*	*Strategies*	*Awareness*	*Knowledge*	*RMP*
Risk identification techniques	CC	1.000				
Strategies	CC	.531**	1.000			
	Sig.	<.001				
Awareness of risk management system	CC	.285*	.484**	1.000		
	Sig.	.041	<.001			
Knowledge of risk management practice	CC	.576**	.675**	.680**	1.000	
	Sig.	<.001	<.001	<.001		
Risk management practice	CC	.422**	.476**	.501**	.569**	1.000
	Sig.	.002	<.001	<.001	<.001	

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

CC: Correlation coefficient

Table 11: Profile of pharmaceutical manufacturing companies in Ethiopia, 2024 (N = 6)

Variables	*Status*	*Frequency*	*Companies*					
			1	*2*	*3*	*4*	*5*	*6*
Training	Partially trained	4	√	√			√	√
	Fully Trained	2			√	√		
Work load	High	2	√				√	
	Medium	3			√	√		√
	Low	1		√				
Government support	Yes	4	√	√	√	√		
	No	2					√	√

Note: '√' means 'Yes', 1, 2,3,4,5 and 6 represent companies

As observed in Table 12, the Fisher-Freeman-Halton test results for risk management practice revealed that only employee workload is negatively and significantly associated with risk management practice (p = .003). This finding indicates that an increase in employee workload is significantly correlated with a decrease in the effectiveness or level of risk management practice within the pharmaceutical companies.

Table 12: Fisher-Freeman-Halton test results for risk management practice

*Risk management practice**	*Test statistic*	*Exact sig. (2-sided)*
Training	15.336	0.248
Current work experience	33.216	0.248
Government support	10.731	0.937
Total work experience	15.687	0.195
Education level	50.264	0.223
Employees Profit	47.022	0.17
Work load	12.610	.003

Note: RMP= Risk Management Practices, PAT = Process Analytical Technology

Assessment of Common Reasons for Deviations from cGMP

Table 13 outlines respondent perceptions regarding factors contributing to cGMP deviations. The highest confidence was reported in quality control and testing (M = 4.27, SD = 0.828, p < 0.001) and change control management (M = 4.03, SD = 1.066, p < 0.001), indicating robust compliance in these core areas. Proper documentation (M = 3.97) and personnel training (M = 3.87) also received positive ratings, though high variability suggests a need for more consistent application. While raw material quality and process validation received moderately high scores, significant concerns were identified regarding equipment and facility issues, which received the lowest rating (M = 3.30, SD = 0.915, p = 0.803), reflecting gaps in maintenance and calibration. Additionally, high standard deviations for

Table 13: Common reasons for deviations from CGMP (N = 30)

Items	*Mean*	*Median*	*Mode*	*SD*	*p-value*	*95% CI*	
						Lower	*Upper*
cGMP based adequate training of personnel involved in manufacturing	3.87	4	4	1.137	.002	.87	1.34
Proper documentation, complete or accurate records, including batch records and standard operating procedures (SOPs).	3.97	4	4	0.928	<.001	.73	1.06
Equipment and facility issues: There are no problems with equipment maintenance, calibration and facilities	3.3	3	3	0.915	.079	.73	1.06
Raw material quality issues: The use of standard raw materials	3.77	4	4	0.898	<.001	.60	1.13
Process control and validation issues: Adequate controls over manufacturing process and validate processes	3.8	4	4	1.095	<.001	.89	1.22
Change control management: Changes to processes, equipment, or materials with proper evaluation and documentation	4.03	4	5	1.066	<.001	.64	1.43
Quality control and testing: Adequate quality control processes, including testing methods and equipment	4.27	4	5	0.828	<.001	.63	.96
Supplier and vendor: There are no problems with the quality of components supplied by third-party vendors.	3.7	4	4	0.915	<.001	.70	1.10
Environmental monitoring: Adequate monitoring of environmental conditions, such as temperature and humidity	3.7	4	3	0.988	.001	.56	1.10
Human Error: Mistakes made by personnel during various stages of manufacturing, packaging, or quality control are rare	3.47	4	4	1.167	.051	.90	1.35

Rating scale: 1: very poor to 5: very good

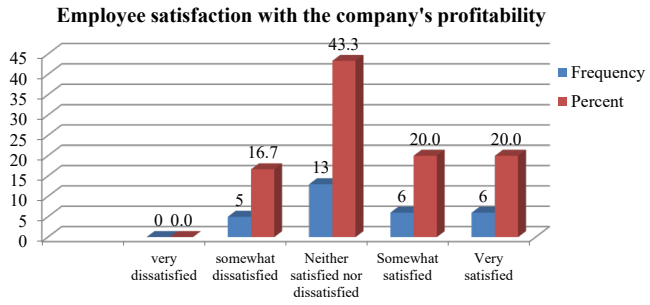

Fig. 4: Respondent satisfaction with profit from pharmaceutical manufacturers, 2024 (N = 30)

human error (SD = 1.67) and environmental monitoring (SD = 1.67) indicate substantial disagreement among respondents regarding the effectiveness of these specific controls.

Employee Profit from the Company

The information on employee satisfaction with profit from the companies is presented in Fig. 4. A majority of workers, 43.3%, state that they are neutral regarding their satisfaction with the company's product profits. This neutral stance is balanced by 20.0% of employees who report being somewhat satisfied and an additional 20.0% who report being very satisfied. However, this positive sentiment is slightly offset by the 16.7% of employees who express some degree of dissatisfaction.

Table 14: Findings on reasons for low profit (N = 5)

Items	*Mean*	*Median*	*Mode*	*Std. deviation*
High production costs	4	4	4	0
Low sales volume	2.5	2.5	1	1.643
Intense competition	2	2	1	1.095
Quality issues	1.5	1.5	1	0.548
Ineffective pricing strategies	3	3	3	0
Overhead expenses	4	4	4	0
Supply chain issues	4.5	4.5	4	0.545
Regulatory compliance costs	2.2	2.5	2	0.548
Technological obsolescence	3	3	3	0
Market fluctuations	4	4	4	0

Reasons for Low Profit from the Companies

Table 14 identifies primary drivers of low profitability using a 5-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree). Supply chain issues emerged as the most significant factor (M = 4.5), followed by high production costs and overhead expenses (both M = 4.0), indicating these are the critical financial pressures facing the sector. Factors such as ineffective pricing strategies and technological obsolescence showed moderate impact (M

= 3.0). Interestingly, respondents perceived regulatory compliance costs (M = 2.2) and low sales volume (M = 2.5) as less significant. Intense competition (M = 2.0) and quality issues (M = 1.5) received the lowest scores, suggesting that manufacturers view internal operational and supply inefficiencies—rather than market competition or quality failures—as the primary threats to their financial health.

Discussion

Risk Management Practice in Pharmaceutical Companies

The finding that all companies had generally sound risk management procedures, yet observation indicated systems ranging from minimal to moderate due to informal practices and limited documentation, points to a critical scientific distinction: the difference between intent and formal implementation. The presence of informal practices suggests that risk awareness exists at the operational level, but the formal quality risk management (QRM) system lacks maturity.[11]

This undocumented approach introduces variability and reliance on individual knowledge, fundamentally violating the principles of a robust, reproducible pharmaceutical QMS. According to ICH Q10 (Pharmaceutical Quality System), QRM must be integrated and documented systematically. The lowest score for "Mitigating Risks" is the practical outcome of this issue. If risk identification and assessment are inconsistent, the resulting mitigation strategies will naturally be insufficient, leading to continued exposure to known operational vulnerabilities, despite the existence of foundational frameworks. [16]

Evaluation of Risk Management Systems in the Post-Marketing Phase

The data revealing that a significant portion of companies lack adverse event reporting systems (AERS) and formal signal detection and analysis processes, despite having policies for recalls and complaints, indicates a fundamental gap in pharmacovigilance. [17]

Post-marketing risk management is split into reactive management (handling known problems like recalls/ complaints) and proactive surveillance (detecting unknown or emerging risks). The high compliance with reactive systems versus the low adoption of proactive systems, signal detection, shows Ethiopian pharmaceutical manufacturers are managing the consequences of risk but failing to effectively manage the risk of unknown harm is a core component of post-marketing QRM.[18]

Signal detection is the scientific process of identifying a new or changing safety issue potentially caused by a drug. Without dedicated AERS and signal detection, manufacturers lose the critical feedback loop necessary to update the product's risk-benefit profile.[17] The low use of post-market clinical studies further restricts the ability to gather long-term safety and efficacy data, confirming a preference for minimal regulatory compliance over comprehensive lifecycle safety management. Similarly, the research conducted by Abbie Barry *et al.* (2020) found that while pharmacovigilance systems were in place, their performance was suboptimal, which aligns with the findings of this study. [19]

Challenges in Implementing Effective Risk Management System

The primary challenge reported difficulties in identifying potential hazards exacerbated by the complexity of pharmaceutical products are a classic indication of insufficient expertise and reliance on simplified tools. The complexity of pharmaceutical processes necessitates highly technical, specialized QRM teams.[13] When only 40% of respondents feel confident in assessing likelihood and impact, it signifies a weakness in the technical competence required to translate complex process variables into quantifiable risk metrics (Severity, Occurrence). This difficulty stems from inadequate process understanding a core principle of pharmaceutical Development.[7]

Risks cannot be accurately identified or assessed unless the underlying manufacturing process variables and their impact on the critical quality attributes are scientifically understood. The ability of 73.3% of respondents to "adapt to evolving risks" might be overstated if their foundational ability to identify and assess those risks is low, suggesting an overconfidence in reactive troubleshooting rather than proactive adaptation.[20]

Frequently Observed Risks in Pharmaceutical Manufacturers

The findings confirm that the primary risks are not quality-related failures but upstream systemic and external disruptions. Regulatory challenges, specifically long approval processes and a lack of clear regulatory guidelines, directly impede the QMS by preventing timely innovation and modification (e.g., updating a process to mitigate a newly identified risk).[21]

In addition, 50% of respondents noted a lack of clear regulatory guidelines within their organizations, creating inconsistency and raising the risk of compliance issues. Regular regulatory inspections, experienced by only 43.3% of respondents, further complicate the compliance process and disrupt daily operations. The difficulty of adapting to constantly changing regulatory requirements was also highlighted by 40% of respondents, who described the process as both challenging and time-consuming. [22]

These findings align with research by P. Brhlikova *et al.* (2015), which points to limited regulatory capacity as a key challenge in Nepal, preventing effective implementation of GMP standards. [23]

In addition to regulatory challenges, Ethiopian pharmaceutical producers face serious supply chain disruptions. A staggering 80% of respondents cited raw material shortages as a major concern. These shortages are largely due to the vulnerability of manufacturers to external shocks in the complex global supply chains they depend on. A 2022 study by L. Curran supports this finding, emphasizing supply chain disruptions as a primary risk for companies during that period.[10] Moreover, 40% of respondents mentioned that delays, logistical issues, and geopolitical factors hinder the timely delivery of raw materials and finished goods, further complicating the supply chain. These interruptions can negatively affect production schedules, reduce product quality, and make it harder for businesses to meet consumer demand. [10]

Operational risks also pose significant challenges. According to 83.3% of respondents, equipment failures are a major issue, leading to delays and downtime in manufacturing, which further reduces overall efficiency.[14] Additionally, 40% of respondents cited various reasons for production delays, such as equipment malfunctions, raw material shortages, and quality control problems. Furthermore, 23.3% of participants pointed to human error as a factor that can lead to compliance violations or product failures, particularly in data entry and manufacturing processes. Another 16.7% of respondents mentioned challenges with quality control, underscoring the importance of maintaining stringent standards to ensure the safety and effectiveness of products. [24]

Financial risks are also a concern for Ethiopian pharmaceutical companies. A significant 70% of respondents identified exchange rate fluctuations as a major issue, affecting cash flow and profitability, especially for companies that operate internationally. Additionally, 33.3% mentioned cash flow problems due to unexpected expenses, high operational costs, or late payments. High operating costs also put pressure on profit margins, as noted by 26.7% of respondents.

These financial challenges mirror findings from P. Brhlikova *et al.* (2015), who noted that financial constraints and a lack of investment in capital improvements are major barriers to implementing GMP standards. [23]

Market concerns also add to the difficulties faced by pharmaceutical businesses. About 70% of respondents cited intense competition from imported drugs as a significant issue, impacting pricing strategies and market share. Environmental and human health risks are also substantial. According to 70% of respondents, waste management is a major concern, as handling large volumes of hazardous waste during manufacturing processes poses risks to both the environment and human health. [10]

Furthermore, 46.7% of respondents mentioned the risk of chemical leaks during production or transport, which can contaminate the environment and pose serious health risks. About 40% of respondents identified exposure to dangerous substances and physically demanding work environments as the main causes of occupational health risks. [13]

To mitigate these complex risks, Ethiopian pharmaceutical companies must actively engage with regulatory bodies to streamline the licensing process and establish clear guidelines. Strengthening relationships with suppliers and diversifying supply chains will help ensure resilience and stability.[25] Investing in preventive maintenance and implementing strict quality control procedures can reduce production disruptions and maintain product quality. Financial risks can be managed through strategies such as currency hedging and detailed cash flow forecasting. By staying on top of market dynamics, companies can adjust their strategies in response to changes in pricing, market saturation, and competition pressures.[11] Finally, prioritizing occupational health and safety and environmental protection can help minimize the risks associated with manufacturing processes. By addressing these five critical areas, Ethiopian pharmaceutical companies can improve operational efficiency, ensure regulatory compliance, and maintain a competitive edge in the global market.[24]

Risk Identification Techniques

This study examined respondents' views on the usefulness of standard tools and their knowledge of risk identification methods in pharmaceutical manufacturing. The results showed that 36.7% of respondents use brainstorming sessions 'sometimes,' suggesting that its use varies. This could indicate that manufacturers are either less familiar with brainstorming or not fully aware of its potential. Since brainstorming leverages organizational knowledge and creativity to enhance risk management, it is considered a valuable method for risk detection. Consequently, pharmaceutical producers are highly encouraged to employ it. [7] Furthermore, a 2020 study by Ismael OA and Ahmed MI demonstrated the effectiveness of the QRM technique, which includes brainstorming, in identifying potential risks. [13]

Root cause analysis (RCA) is widely regarded as one of the most effective risk management techniques, particularly within the pharmaceutical industry. Checklists have become the most widely utilized tool, along with RCA. In risk management, both RCA and checklists are essential. While RCA concentrates on locating and resolving the underlying causes, checklists make sure that procedures are followed exactly, which enhances operational effectiveness, safety, and compliance. [22,23]

Conversely, a strengths, weaknesses, opportunities, and threats (SWOT) analysis demonstrates a more diverse use across companies, with 33.3% of respondents saying that it is employed "sometimes." This implies that some companies could not completely appreciate SWOT

analysis's strategic relevance in assessing internal and external risk factors. However, when used properly, SWOT analysis can support strategic thinking and well-informed choices. Consequently, it is advised that businesses use this method more frequently to improve their risk management systems. To identify risks, failure mode and effects analysis (FMEA) is essential. According to the assessment, 53.3% of respondents indicated its "sometimes" usage. To improve risk management, companies should encourage more frequent use of FMEA to proactively identify potential failures, incorporate scenario analysis to address less obvious risks, and integrate multiple tools to develop a comprehensive risk identification strategy. [27]

In summary, the findings emphasize the importance of specific methods, particularly checklists, RCA, and brainstorming, in improving risk management practices in the pharmaceutical manufacturing industry. The results also suggest potential areas for further research, such as exploring how these methods interact and are used in different contexts within broader risk detection frameworks. By expanding their strategies and regularly evaluating the effectiveness of these tools, pharmaceutical companies can boost operational efficiency, ensure patient safety, and strengthen their overall risk management processes. [13]

Common Reasons for Deviations from cGMP

The identified reasons for deviations from cGMP—including facility/equipment issues, inadequate environmental monitoring, and human error—underscore a lack of control over fundamental quality system elements. Equipment and facility issues (like poor calibration or maintenance) point to failures in the ICHQ10 maintenance subsystem, directly impacting process reliability. [28]

Inadequate monitoring of environmental conditions (humidity/temperature) compromises the stability and quality of the final drug product, particularly those sensitive to moisture or heat. Crucially, human error, which is a significant factor globally, necessitates a shift from punitive action to systemic correction. This requires human factors engineering simplifying tasks, improving clarity of standard operating procedures, and integrating automation to reduce reliance on manual data entry or complex operations.[29] The findings here (equipment and facility issues) differ from study conducted by Wölfle *et al*. (2021) in Germany, cited (employee carelessness), suggesting that in the Ethiopian context, infrastructure and maintenance deficits are potentially more dominant contributors to cGMP deviations than purely behavioral factors, although both are ultimately linked to training and QMS maturity. [20]

Organizations should establish a thorough preventive maintenance program, provide detailed training with clear instructions to reduce human error, and implement strong environmental monitoring practices to address these issues and minimize deviations. Regular audits, inspections, and performance evaluations will improve product quality and patient safety while helping ensure compliance with GMP regulations.[16] Additionally, improving employee satisfaction by identifying the root causes of dissatisfaction and taking corrective action can boost productivity, attract potential hires who might be put off by negative reviews, and strengthen employee loyalty—ultimately leading to better output quality. [30]

Limitations of the Study

The purpose of this study was to assess quality risk management systems in Ethiopian pharmaceutical manufacturers, serving as a basis for further investigation. However, the study was unable to monitor changes in performance over time due to the lack of prior reports on risk management in Ethiopia. There was no causal analysis or follow-up on non-compliance with risk management processes because the study was cross-sectional. Additionally, the survey was conducted solely among six pharmaceutical manufacturers located in Addis Ababa and Sheger City, with a limited number of key respondents participating. The study lacked representation across the full organizational hierarchy, from security personnel to top-level executives. Therefore, future nationwide surveys and intervention studies are needed to provide a more comprehensive understanding of QRM system and identify areas for improvement based on the findings of this study.

Conclusion

The study assessed QRM systems, revealing that formal risk management systems were not always used, despite good performance in risk identification, assessment, and monitoring. Companies had system in place for monitoring product complaints and handling recalls, but they did not fully utilize important tools like pharmacovigilance and adverse event reporting. Operational risks were also major concerns, including financial difficulties, shortages of raw materials, and equipment malfunctions. By investing in technology, diversifying supply chains, and expanding training, the report suggested strengthening risk mitigation techniques. Additionally, it underlined how crucial it is to increase employee awareness in order to improve compliance and lower risks, particularly with regard to regulatory standards and risk management tools. The results highlight the necessity of continual improvement in training, resource allocation, and risk management practices to guarantee the safety, quality, and effectiveness of the product in Ethiopia's pharmaceutical manufacturers.

Ethics Approval and Consent to Participants

A letter of permission and ethical approval, bearing the reference number' JUIH/IRB/198/24', was obtained from the Institutional Review Board (IRB) of Jimma University, Institute of Health, before data collection on May 6, 2024. The purpose of the study was thoroughly explained to the

participants, and written informed consent was obtained from all study subjects. Additionally, the confidentiality and anonymity of the data were maintained by the investigator and research assistants throughout the study.

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