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The Study of Effectiveness of Risk Management and Its Impact on Organizational Performance of Pharmaceutical Industry of Pakistan

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Critical success factors (CSF), Effectiveness of Risk Management (ERM), Organizational performance (OP), clear communication (CC), Good leadership (GL), Regulatory compliance (RC), organizational culture (OC), training/ competency (TAC)

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Abstract: *The purpose of this study is to examine the relationship between critical risk factor (CRF)/ critical success factors (CSF) and effectiveness of risk management (ERM), and in turn its relationship with organizational performance (OP) through mediating effect of ERM. Five critical risk factors included in this study are clear communication (CC) of risk, Good leadership (GL), Regulatory compliance (RC), organizational culture (OC), and training/ competency (TAC) of employees to identify assess and control risk associated with pharmaceutical industry of Pakistan. Organizational performance was taken in term of reduction in product failure, improving product quality, increasing confidence on product safety, reduction of cost and preventing rework. Data were collected using an online questionnaire on Google form, sent to private and public sector organizations located within Pakistan. The data analysis and hypotheses testing were performed using correlation analysis, regression and structural equation modeling using smart PLS. The results showed that all five CSF positively affect the effectiveness of risk management. Effectiveness of risk management also showed a significant positive effect on organizational performance both directly and through mediation between CSF and organizational performance. The results can help management at all level to a better understanding of the linkage between CSF, ERM and organizational performance. They could use the results of this study to design their ERM practices accordingly. To the authors' best knowledge, this paper is the first empirical study within pharmaceutical industry of Pakistan that has investigated the relationship between CSF, ERM and organizational performance.*

Introduction

A systematic process for evaluating, controlling, communicating, and reviewing risks to the quality of the medicinal product throughout the product lifecycle is quality risk management" Ali and Hajela (2011).

Effective risk management (ERM) is essential for pharmaceutical industry to manufacture Quality, safe and effective medicinal products which guaranteed the availability of safe and effective product for patients use (Ismael & Ahmed, 2020; Vartak & Bhagure, 2012). ERM and its procedures assist a company to identify possible hazards, assess their consequences, and plan action to lessen and control those consequences (Charoo & Ali, 2013). There are significant number of compliance risks as well as numerous other risks that are present in markets around the world, including supply chain issues, quality, cyberattacks, data integrity breaches, geopolitical exposure, and risks from third and fourth parties (Dhankhar et al., 2018).

Risk management is important strategy in pharmaceutical sector which cannot be ignored. Risk management includes a broad range of activities throughout the life cycle of pharmaceutical product, starting from preclinical research and clinical trials to manufacturing, distribution, and post-market surveillance (Vartak & Bhagure, 2012). Literature also showed that effectiveness of Risk management in any organization largely depends upon CSF including but not limited to organizational culture, training/competency, leadership, regulatory guidelines and communication. Additionally, it also contributes to performance and efficiency of pharmaceutical industry by reducing downtime, preventing operational faults or product failure, and enhancing overall process reliability.

In Pakistan, the pharmaceutical industry plays a dynamic role in establishing and managing healthcare system, providing essential drugs and medication to a population of over 220 million people. However, the pharmaceutical industry of Pakistan faces several challenges that can impact its operational performance. These include regulatory compliance issues, quality control issues, supply chain vulnerabilities, and limited access to advanced technologies due to lack of competency or financial issues. The need for robust risk assessment and risk management practices is necessary, as they can help to mitigate these challenges and ensure the availability of quality and safe product to the people (Alsaidalani & Elmadhounb, 2021).

This study aims to provide a thorough understanding of risk, critical risk factors for effective risk management, and the impact of effective risk management on the operational performance of the pharmaceutical industry. With the ultimate objective of increasing the efficacy of risk management techniques in Pakistan's pharmaceutical industry. The research was expected to provide a foundation for evidence-based recommendations that can enhance Risk Management practices, ultimately ensuring the delivery of safe, efficacious, and high-quality pharmaceutical products to the Pakistani population.

Statement of the problem

On the basis of research gap identified, the aims were to identify the relationship between critical risk factors and effectiveness of risk management, and overall performance of industry.

Study Objective

- To assess the relationship between risk management system and organizational performance.
- To identify and analyze the relationship of critical success factors for effective implantation of risk management system in pharmaceutical companies in Pakistan.

Literature Review and Hypothesis

Risk Management and its Component

According to Anderson and Terp (2006), “Risk Management is a process that can be used to eliminate, Reduce and control the critical risk and enhance benefits.” Pharmaceutical industry encounters different types of risk. For example, risk associated with raw material variability that affects the quality of drug or medicine (Carlin, 2016). Failure Modes and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and the use of risk matrices are some fundamental tools providing foundation for

identifying, analyzing, and mitigating risks in pharmaceutical industry (Carlin, 2012). Quality Risk Management (QRM) in pharmaceutical industry during manufacturing is now becoming an essential part of QMS. Regardless of criticality of step, regulatory bodies incorporated risk assessment in each step starting from raw material to final product (Alsaidalani & Elmadhounb, 2021).

According to (Partnerships BC, 2005), the process of risk management consists of eight steps: (1) Establishing the context (2) Identifying (3) Analyzing (4) Evaluating (5) Developing the risk mitigation strategy (6) Monitoring and Reviewing the risk mitigation strategy (7) Quantifying the risks and (8) Consulting and communicating the risk. As per ICH guidelines, Quality Risk Management (QRM) process and its components are illustrated in **Figure1**.

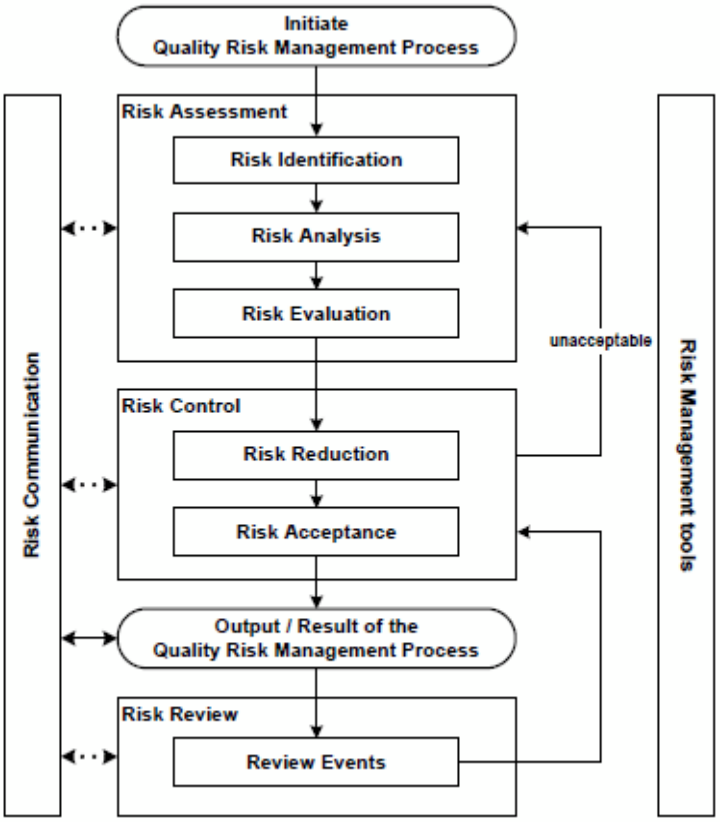

Figure 1: Systematic model for the quality risk management system

Critical Success factors

Rochart, (1979 cited in Jha and Dinesh (2024)), was first to define the concept of critical success factors for effective risk management in organization. These Critical success factors were defined as "The limited number of areas in which results, if they are satisfactory, will ensure successful competitive performance for the organization. They are the few key areas where things must go right for the business to flourish. If results in these areas are not adequate, the organization's efforts for the periods will be less than desired." Baba et al. (2006) defined Critical success factor as "a range of enablers which, when put into practice will enhance the chance for successful benchmarking implementation and adoption in an organization." Drawing conclusion on definition of Critical success factor within the context of this study, are defined as drivers or enablers for effective and successful implementation of risk management system in an organization. Different authors have different opinion about the number and type of the critical factors that influence the overall performance of the organization. Inadequate machine maintenance, Disruptions between production and warehousing, Shifts in wage rates for employees, Political instability are major obstacle to improving supply chain operational performance of the

organization (Sreedharan et al., 2019). As Communication, Organizational Culture, Organizational Structuring and Design, Trust (Grabowski & Roberts, 1999), Top-level management support, Acknowledgment that risk is reality, Commitment to identify and manage risks (Galorath, 2006), Verifying your judgments, Change management, Embedding risks developing of risk training course, the importance of sound judgment, Identification Issues, Assessing the importance of risk (Carey, 2001), Leadership, Culture, Structure, roles, and responsibilities, Information technology infrastructure, Measurement (Hasanali, 2002), management of talent, leadership development, a risk-aware culture, artificial intelligence, block chain, and the Internet of Things (Olawale et al., 2024), are most important factors in view of different researchers. According to Yusof and Aspinwall (2000), CSFs for TQM implementation is "management leadership, continuous improvement system, measurement and feedback, improvement tools and techniques, supplier quality assurance, human resource development, systems and processes, resources, education and training, and work environment and culture". According to Hodgetts et al. (1999), the CSFs of TQM implementation is "top management involvement, customer focus, employees "training, employees' empowerment and generating new ideas" Based upon literature review five critical success factor were taken for this study to examine their relationship with ERM and OP as follows.

Communication is an important ability for leaders and senior management to ensure that the team members understand and support all the activities and their set goals (Clutterbuck & Hirst, 2002). According to (Finniston, 1975), gathering, storing and delivering and communicating information is helpful in growing business which make the employees of the organization updated with the recent developments about the risk. Grabowski and Roberts (1999) emphasized that communication during mitigation of risk provides the opportunity for employees concern to learn about the event taking place around them and their impact. Zameer (2017) also believes that for effective risk management, it is important for a pharmaceutical industry to have a proper management for controlling and handling of different types of risks and these risks should be defined clearly, effectively and communicated to team member and other employees. Abu Kwaik et al. (2023) identified "communication" as a critical success factor for effective risk management along 23 other and found a significant positive effect on ERM. Above discussion leads us to propose a hypothesis based upon literature review

H1: *There is a relationship between Clear Communication and ERM*

Top management support is a very important critical success factor for better decision making, quality risk culture and ways how to handle critical risks. This shows the much-needed support, efforts and approval from top leadership for risk management (Jha & Dinesh, 2024). To identify and manage risk effectively require a support and commitment from top management (Galorath, 2006). Hasanali (2002) identified different CSFs for effective implementation of risk management system and found that leadership and its commitment is one of the important factors which provide basic support for implantation of risk management system. Zameer (2017) identified good leadership as critical success factor for ERM in pharmaceutical industry. Abu Kwaik et al. (2023) identified "Top management" as a critical success factor for effective risk management along 23 other and found a significant positive effect on ERM. Above discussion leads us to propose a hypothesis based upon literature review

H2: *There is a relationship between Good Leadership and ERM*

Zameer (2017) identified that good leadership, clear communication, and organizational culture are most important and success factors for ERM. The research emphasizes that leadership behaviors directly influence the organization's ability to identify, assess, and mitigate and communicate risks, ensuring compliance with regulatory standards and protecting patient health. Organization with good and

medium organizational culture shows successful implementation of management system (Mohammad Mosadegh Rad, 2006). The FDA Group's article in 2017 highlights that integration of QRM into the organizational culture ensures quality of product and patient safety across all operations. Organizational culture has positive impact of organizational performance through mediating effect of ERM (Lee, 2024). Abu Kwaik et al. (2023) identified "organizational culture" as a critical success factor for ERM and found a significant positive effect on ERM. Above discussion leads us to propose a hypothesis based upon literature review

H3: *There is a relationship between Organizational culture and ERM*

According to Moeuf et al. (2020), the most important critical success factors for implementation of risk management system to evaluate and control the risk is employees training. Dale S. Beach (as cited in Jha and Dinesh (2024)), defines training as 'the organized procedure by which people learn knowledge and/or skill for a definite purpose. It develops a person attitude, ability and specific skills to a required level of satisfactions which makes the organization to lift their employees to the level where they perform their duties as per required level. Training of employees is among the most important factors for implementation of management structure including TQM (Hodgetts et al., 1999). The development of risk training course is also important factors which provide the risk awareness to team member (Carey, 2001). Above discussion leads us to propose a hypothesis based upon literature review

H4: *There is a relationship between Training and Competency and ERM*

Regulatory compliance culture along with regulatory bureaucracy and senior management support are major critical success factors (O'callaghan et al., 2022). According to Dhankhar et al. (2018)**,** it is necessary for pharmaceutical companies to broaden the risk management system framework against recently emerging threats or risks particularly including regulatory changes or regulatory compliance issues in pharmaceutical sectors. Zameer (2017) also concluded that the most important risk associated with the pharmaceutical industry is a regulatory risk. Abu Kwaik et al. (2023) also identified "government rules and regulations" as CSF for effective risk management and has positive effect on ERM. Above discussion leads us to propose a hypothesis based upon literature review

H5: *There is a relationship between Regulatory Compliance and ERM*

Effective risk management is important for improving the performance of the organization and both are positive correlated (Saleem & Abideen, 2011). According to Mu et al. (2009), "understanding, identifying, managing, and reducing the risk is of strategic importance for firms and appropriate risk management strategies can significantly improve the odds of new product development success. Knowledge risk management positively impacts the agility of organizations and Furthermore, Organizational performance is positively affected by risk management mechanisms (Durst et al., 2019). ERM implementation has significant impact on the organizational financial and non-financial performance (Teoh, 2009). Enterprises risk management implementation has a significant positive impact on organization performance and business strategy (Soltanizadeh et al., 2014). Effective interaction of risk management and internal control system with organization culture prevent the operational failure and increase the organizational performance (Lee, 2024). According to Waldron (2017), the potential advantage of quality risk management is improved drug quality and ultimately the patient safety. According to Thomya and Saenchaiyathon (2015), organizational culture may affect ERM positively and ERM in turn has a positive relation with organizational performance. Effective risk management positively influence the performance of the organization (Yahaya et al., 2015). Above discussion leads us to propose a two-hypothesis based upon literature review and to fill the research gaps.

H6: *There is a relationship between ERM and Organizational Performance****.***

H7: *There is the mediation effect of ERM between each individual I.V and the organizational performance.*

Theoretical Framework

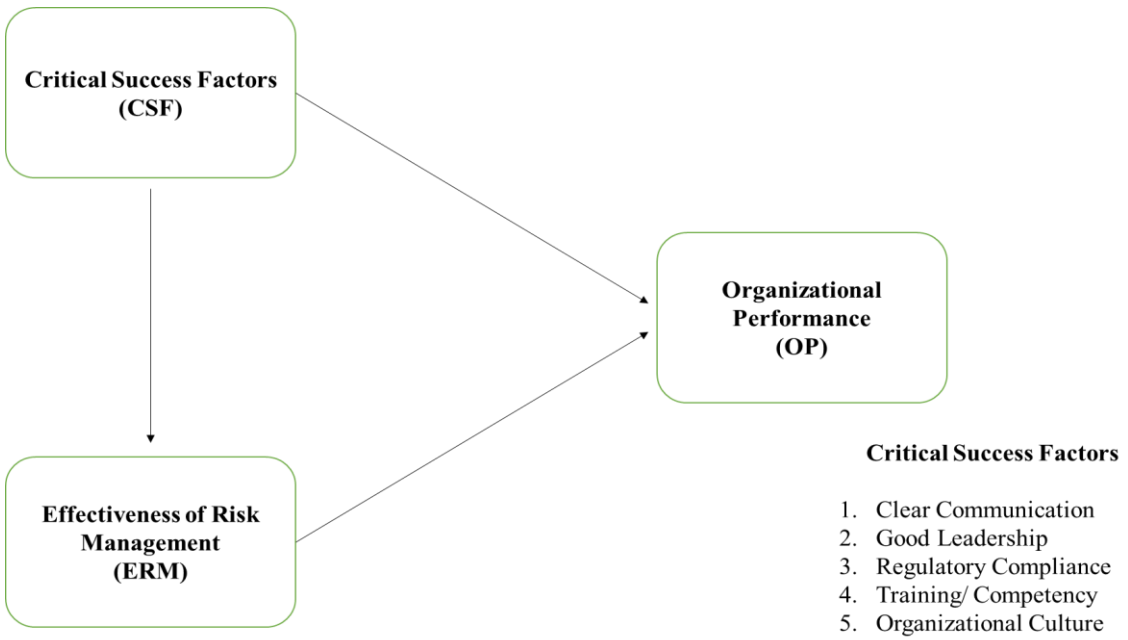

Figure 2: Theoretical Framework

Research Design/Population/Sampling

A cross-sectional descriptive research design using surveys and literature review was adopted for this study. The primary objective is to assess how effective risk management practices influence organizational performance within pharmaceutical companies in Pakistan. A quantitative study was conducted through online self-administered questionnaire using google form with targeted value of collecting 250 responses from different pharmaceutical sector in Pakistan. Google form survey link is distributed through electronic means to the targeted professionals belonging to pharmaceutical industries of Pakistan. During online survey recording data, the person was allowed to submit only one response against structured questionnaire.

Research Instrument Development and Design

The questionnaire divided into the following sections including Section 1 (Demographic Information), Section 2 (Risk Success factors), Section 3 (Risk and Risk management Awareness), Section 4 (Risk Management vs Organization Performance). In Section 2 and section 4, questions were asked on 5-point Likert scale (1: Strongly Disagree to 5: Strongly Agree). Organizational Performance's questions were related to Cost of Production, Waste Production, Improving in Drug Quality, Improving delivery Performance, Revenue Growth, Product development, Reduction in product failure, Reduction in process failure and Reduction in Recall of product.

Data Analysis Techniques

To summarize demographic data and risk management practices a descriptive statistic was performed to get overview of data collected. Inferential Statistics including Pearson correlation, Regression analysis and Structural Equation Modeling (SEM) technique was used to test all hypothesis.

Results & Findings

Descriptive Statistics

About 250 questionnaires are distributed among the professionals of pharmaceutical sectors through google survey form. Among the 250 questionnaires, 185 responses are received with the response rate of 74.0 % which is good sample size for further analysis. The demographic breakdown of is as follow:

Table 1: Demographic characteristics

Variable	Category	Frequency	Percentage (%)
Age group	20-30	22	11.9
	31-40	140	75.7
	41-50	22	11.9
	51-60	1	0.5
	>60	-	-
Gender	Male	122	65.9
	Female	63	34.1
Qualification	Graduation	31	16.76
	Master	117	63.24
	MPhil	23	12.43
	PhD	14	7.57
Experience	Less than 2 years	6	3.2
	2-5 Year	24	13.0
	6-10 Year	107	57.8
	>10 Year	48	25.9

Response collected through Google form against age group shows that about 75.7 percent professionals belong to age group of 31 to 40 years and 11.9 % professionals belong to age group of 41-50 years including 65.9 % male and about 34.1 % female professionals. 84.9 % respondents are Master or above with total experience greater than 6 years, suggesting that a large number of the responders have significant professional experience.

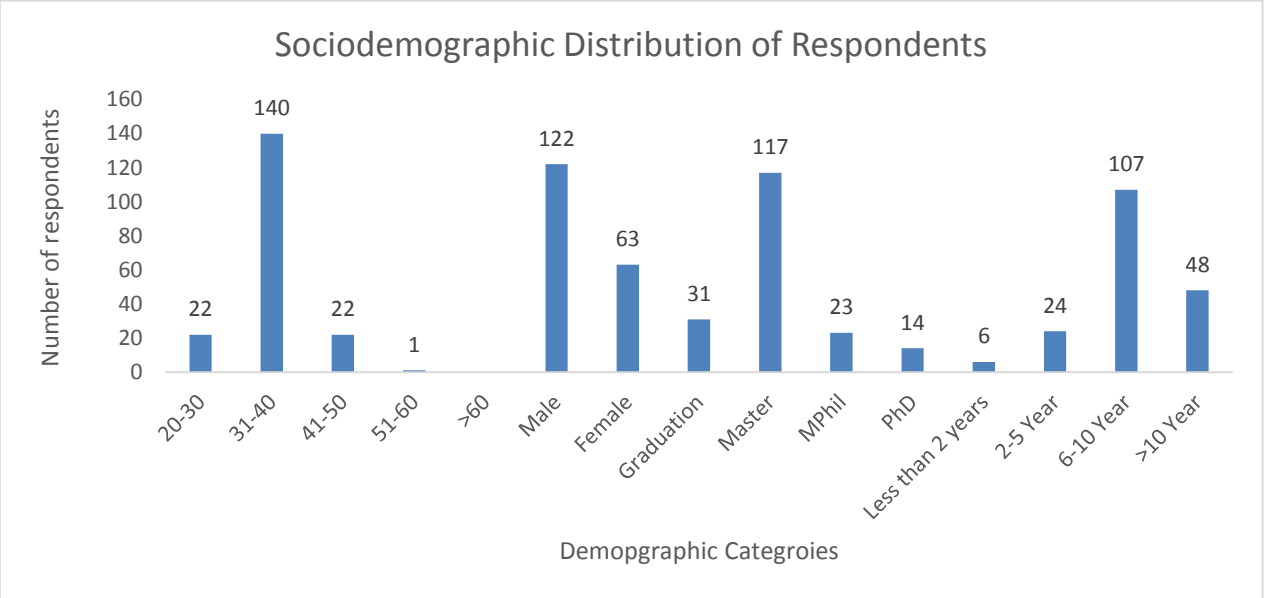

Figure 3: Demographic Characteristics

Descriptive Analysis was performed using SPSS and found that median of all individual variables was equal to or greater than 4.00. Hence overall Perceptions of all variables were generally positive and fairly consistent across all groups.

Table 2: Descriptive analysis of all variables

Variable Name	Total Response	Minimum	Maximum	Mean	S. D	Q1	Median	Q3
Good Leadership	185	3.00	5.00	4.36	0.42	4.00	4.20	4.80
Regulatory Compliance	185	3.00	5.00	4.34	0.44	4.00	4.17	4.83
Training/Competency	185	3.00	5.00	4.44	0.43	4.00	4.33	4.83
Organizational Culture	185	3.00	5.00	4.36	0.45	4.00	4.17	4.83
Effectiveness of risk management	185	2.50	5.00	4.08	0.48	4.00	4.00	4.17
Organizational Performance	185	2.45	5.00	4.26	0.54	4.17	4.50	4.83
Clear Communication	185	3.33	5.00	4.49	0.39	3.91	4.27	4.73

Data Reliability

Table 3: Overall Cronbach's alpha value for each variable

Variable Name	No. of items	Cronbach's alpha	Cronbach's alpha (Pilot study)
Clear Communication	6	0.820	0.792
Good Leadership	5	0.843	0.670
Regulatory Compliance	6	0.879	0.860
Training/Competency	6	0.862	0.778
Organizational Culture	6	0.919	0.882
ERM	7	0.908	0.874
Organizational Performance	11	0.913	0.744

Sample size N= 185

Data collected through online Google survey and analyzed using SPSS to find the internal consistency of the variables. Data revealed that in both cases, before and after study the Cronbach's alpha value is greater than 0.7 except Good Leadership (0.670) but after refining the construct this value increased to 0.843. These values validate the fact that every construct consists of a high internal consistency and reliability measure.

Inferential Statistical Analysis

Pearson correlation was performed to measures the strength and direction of a linear relationship between continuous variables. All five independent variables were found to be positively and

significantly correlated with ERM. Good Leadership and Regulatory Compliance demonstrated a moderate positive correlation with Effectiveness of Risk Management with (r = .45, **p** < .01) and (r = .46, **p** < .01) respectively. Training Competency, Organizational Culture and Clear Communication were also significantly associated with risk management outcomes (r = .39, **p** < .01), (r = .44, **p** < .01), and (r = .36, **p** < .01) respectively, highlighting the role of these factors in promoting risk awareness. All five independent variables were found to be positively and significantly correlated with OP. Organizational Culture showed positive correlation with Organizational Performance (r = .34, **p** < .01). Regulatory Compliance (r = .28, **p** < .01) and Training Competency (r = .25, **p** < .01) also demonstrated moderate positive associations. Good Leadership was significantly but weakly correlated with Organizational Performance (r = .20, **p** < .01) while Clear Communication showed the weakest correlation with performance (r = .15, p < .05), though still statistically significant. While ERM positively and significantly correlated with organizational performance (r = .37, **p** < .01).

Table 4: Statistics of Correlation analysis

	Variables	**Correlation with ERM**	**p value**	**Correlation with OP**	**p value**
1	GL	0.45	p > 0.01 (positive)	0.20	p > 0.01 (positive)
2	RC	0.46	p > 0.01 (positive)	0.28	p > 0.01 (positive)
3	TAC	0.39	p > 0.01 (positive)	0.25	p > 0.01 (positive)
4	OC	0.44	p > 0.01 (positive)	0.34	p > 0.01 (positive)
5	CC	0.36	p > 0.01 (positive)	0.15	p > 0.01 (positive)

Significance and explanatory power R2 to check whether the effect of the I.V on the D.V is significant or not, Simple and multiple linear regression analysis was performed. In Simple linear regression the R Square of all models were in the range of 0.132 to 0.209 and coefficient value 0.364 to 0.457.

Table 5: Simple Linear Regression Results Predicting ERM

Hypothesis	**Predictor**	**B**	**SE**	**B**	**T**	**P**	**R^2**	**F Change**
H1	Clear Communication	.446	.084	.364	5.282	< .001	.132	27.899
H2	Good Leadership	.514	.075	.450	6.813	< .001	.202	46.418
H3	Regulatory Compliance	.495	.071	.457	6.944	< .001	.209	48.220
H4	Training & Competency	.433	.077	.386	5.657	< .001	.149	32.002
H5	Organizational Culture	.475	.071	.445	6.716	< .001	.198	45.100
H6	ERM	.414	.077	.368	5.359	< .001	.136	28.717

Note. N = 185 ***p < .001

In multiple linear regression analysis is employed at 95 % confidence interval showed a good model fit F (5,179) = 13.302, p <.001. This model described the variance in dependent variable by 27.1% as (R^2 = .271), and the adjusted R^2 was 0.251. All five I.V were statistically significant positive predictors of effectiveness risk management as illustrated in table.

Table 6: Linear Regression Coefficients of all five I.V on ERM

Variable	B	Std. Error	Beta	T	Sig
(Constant)	1.184	.390		3.035	.003
Good Leadership	.221	.119	.193	1.848	.048
Regulatory Compliance	.209	.101	.193	2.063	.039
Training Competency	.193	.115	.141	1.678	.041
Organizational Culture	.219	.110	.205	1.995	.039
Clear Communication	.213	.109	.139	1.951	.049

Note. N = 185 ***p < .001

Hypothesis Testing (SEM-PLS)

To test the structural relationships among the independent variables, Mediator and dependent variable and to assess the hypothesized mediation model, Structural Equation Modeling (SEM) was performed using Smart PLS. All individual models were statistical positive and good model fit with p < .001. All hypotheses tested and accepted by SEM-PLS.

a) For hypothesis H1, the direct effect of Clear Communication → Effectiveness of Risk Management (β = 0.364, t = 5.126, p < .001), showed a significant positive effect of clear communication on ERM practices in pharmaceutical industry of Pakistan. Hence hypothesis H1 accepted.

b) For hypothesis H2, the direct effect of Good Leadership → Effectiveness of Risk Management (β = 0.450, t = 6.698, p < .001), showed a significant positive effect of Good Leadership on ERM practices in pharmaceutical industry of Pakistan. Hence hypothesis H2 accepted.

c) For hypothesis H3, the direct effect of Regulatory compliance → ERM (β = 0.450, t = 6.698, p < .001), showed a significant positive effect of Regulatory compliance on ERM practices in pharmaceutical industry of Pakistan. Hence hypothesis H3 accepted

d) For hypothesis H4, the direct effect of Training/Competency → Effectiveness of Risk Management (β = 0.386, t = 5.262, p < .001), showed a significant positive effect of Training/Competency on ERM practices in pharmaceutical industry of Pakistan. Hence hypothesis H4 accepted.

e) For hypothesis H5, the direct effect of Organizational Culture→ Effectiveness of Risk Management (β = 0.445, t = 6.199, p < .001) showed a significant positive effect of Organizational Culture on ERM practices in pharmaceutical industry of Pakistan. Hence hypothesis H5 accepted.

f) The direct effect of Effectiveness of Risk Management → Organizational Performance β = 0.368, t = 5.165, p = .0001 showed a significant effect. Hence hypothesis H6 accepted.

g) To assess the mediating role of ERM between CSF and OP, SEM-PLS results showed that the values for indirect effect of Clear communication on organizational performance via ERM was β = 0.131, p = 0.003, Good Leadership to organizational performance via ERM was β = 0.158, p = 0.001, Regulatory Compliance to organizational performance via ERM was β = 0.054, p = 0.077, Training/Competency to Organizational Performance via ERM was β = 0.123, p = 0.002 and organizational culture to

Organizational performance via ERM was β = 0.122, p = 0.003. Hence H7 is accepted.

Table 7: Summary Results of SEM-PLS for Hypothesis and mediation Analysis

I.V	Path Direction	Coefficient β	p value	Results	Full/Partial mediation
CC	CC ➡ ERM (Direct)	0.364	< 0.001	Significant	Full Mediation
	CC ➡ OP (Direct)	0.019	0.817	Non-significant	
	ERM ➡ OP (Direct)	0.361	< 0.001	Significant	
	CC ➡ OP (indirect)	0.131	0.003	Significant	
GL	GL ➡ ERM (Direct)	0.450	< 0.001	Significant	Full Mediation
	GL ➡ OP (Direct)	0.039	0.623	Non-significant	
	ERM ➡ OP (Direct)	0.351	< 0.001	Significant	
	GL ➡ OP (indirect)	0.158	0.001	Significant	
RC	RC ➡ ERM (Direct)	0.457	< 0.001	Significant	Full Mediation
	RC ➡ OP (Direct)	0.140	0.102	Non-significant	
	ERM ➡ OP (Direct)	0.305	< 0.001	Significant	
	RC ➡ OP (indirect)	0.139	0.002	Significant	
OC	OC ➡ ERM (Direct)	0.445	< 0.001	Significant	Partial Mediation
	OC ➡ OP (Direct)	0.214	0.008	significant	
	ERM ➡ OP (Direct)	0.273	< 0.001	Significant	
	OC ➡ OP (indirect)	0.122	0.003	Significant	
TAC	TAC ➡ ERM (Direct)	0.386	< 0.001	Significant	Full Mediation
	TAC ➡ OP (Direct)	0.129	0.102	Non-significant	
	ERM ➡ OP (Direct)	0.318	< 0.001	Significant	
	TAC ➡ OP (indirect)	0.123	0.002	Significant	

Discussion and implications

This study showed that CSF has strong effect on ERM and organizational performance through mediating role of ERM by proactive approach of risk management.

Communication is not just an administrative function; it is an essential part of risk identification, assessment, and response (Aven & Renn, 2010; Grabowski & Roberts, 1999; Zameer, 2017), which is important ability for top management to ensure that the team members understand and support all the activities and their set goals (Clutterbuck & Hirst, 2002). Communication is helpful in growing business which make the employees of the organization updated with the recent developments about the risk (Finniston, 1975). The present study also confirmed the findings of Grabowski and Roberts (1999), Abu Kwaik et al. (2023), and (Zameer, 2017), that clearly defined and effectively communicated risk related information provides opportunity for employees concern to learn about the event taking place around them and their impact which increases the organizational performance. Relevant stakeholders at all levels are guaranteed to be aware of potential risks and be able to make appropriate decisions when there is clear, timely, and accurate communication.

Leadership provides clear direction, accountability, and motivation to develop and establish risk management system (Jha & Dinesh, 2024), through which risk is identified and managed effectively (Galorath, 2006; Hasanali, 2002). The performance of the ERP system is positively impacted by top management support (Olawale et al., 2024). Zameer (2017) identified good leadership as critical success

factor for ERM in pharmaceutical industry. Abu Kwaik et al. (2023) identified “Top management” as a critical success factor for effective risk management and found a significant positive effect on ERM. Many previous studies’ results are similar to this study and found that good leadership has positive impact on ERM which provide basic support for effective implementation of risk management strategies. Thus, by providing empirical support for the function of leadership in the risk management paradigm, this study adds to the body of knowledge and improves organizational performance via ERM.

Regulatory risk is the most important risk associated with the pharmaceutical industry and most of time is consumed in handling of this risk to avoid from non-compliance to regulatory requirements (Zameer, 2017). Regulatory compliance culture is major CSF which improves the risk management effectively (Abu Kwaik et al., 2023; O’callaghan et al., 2022). Present study also confirmed the significant positive relationship between Regulatory compliance and ERM. By providing empirical evidence that regulatory compliance is not only a legal requirement but also a catalyst that increases the efficacy of risk management and overall performance of the organization through mediating role of ERM, particularly in developing nations.

Employees training is important critical success factor for implementation of risk management system (Hodgetts et al., 1999; Moeuf et al., 2020), which develops a person attitude, ability and specific skills to a required level of satisfactions (Jha & Dinesh, 2024). Risk based training courses provides risk awareness (Carey, 2001), which improve employees' abilities and productivity, which in turn boosts organizational effectiveness. Present study is in line with other’s studies and found a significant positive impact of training & competency on ERM and on organizational performance via ERM. By directly connecting training and competency to the efficacy of risk management, this study expands on theoretical understandings of how staff development is a crucial component of successful risk-based strategies.

Employees behaviors directly influence the organization’s ability (Zameer, 2017), to identify, assess, and mitigate and communicate risks. Organizations with developed organizational culture shows successful implementation of management system (Mohammad Mosadegh Rad, 2006). The results of present study are similar and in line with the findings of Mohammad Mosadegh Rad (2006), Zameer (2017), Lee (2024) and Tranchard (2018). Organizational culture not only effect ERM but also influence the organizational performance via mediating effect of ERM. A culture that embeds quality and risk awareness where employee behaviors and decisions are aligned with shared organizational values, a culture of mindfulness, continuous vigilance enhances the effectiveness of risk management systems.

Effective risk management positive correlated with organizational performance (Durst et al., 2019; Saleem & Abideen, 2011; Soltanizadeh et al., 2014; Teoh, 2009), which prevent organizations from operational failure (Lee, 2024) and improve the drug quality and ultimately the patient safety (Waldron, 2017). This study also supports the previous studies and found that when risks are systematically identified, assessed, controlled, and monitored, organizational performance get improved in term of regulatory compliance, product quality, and customer trust. Furthermore, present study also supports the findings of Lee (2024) and found that ERM effectively mediate between all five CSF taken for this study and organizational performance. Effective risk identification, measurement, and control are facilitated by strong leadership, a positive corporate culture, regulatory compliance, the development of skilled and competent employees, and open communication of all organizational risks, both internally and externally ultimately enhance the organization's financial and non-financial performance.

Conclusion

There are few studies available on impact of CSF on ERM and OP which provide only a fragmented understanding of the concept. The present study allows us to draw a linkage between CSF for effective

risk management and organizational performance (Via ERM) for academics and practitioners. Empirical evidence is provided through this study about the consequences of CSF on ERM and organizational performance. The results demonstrated that the effectiveness of Effective risk management (ERM) is essential for pharmaceutical industry to ensure Quality, safety and effectiveness of products by risk management of all risk found including but not limited to Drug development issues, product quality or product failure, counterfeit medicine, supply chain issues, cyberattacks, and data integrity breaches.

The overall result of this study has significant implications for Pakistan's pharmaceutical sector. Therefore, pharmaceutical companies should concentrate on creating effective leadership techniques that uphold stringent regulatory compliance and foster a favorable quality culture. Employees must get ongoing training and competency development in order to improve the technical skills and awareness needed for efficient risk control. Lastly, to detect, evaluate, and reduce risks at every step of operations, a strong risk management system should be put in place as a crucial component of the Pharmaceutical Quality System (PQS). When taken as a whole, these techniques will boost the effectiveness, standing, and long-term viability of pharmaceutical companies in Pakistan in addition to improving product quality and regulatory compliance.

This study has some limitations which must be acknowledged for proper interpretation of findings of this research. Firstly, a cross-sectional descriptive research design adopted for this study which capture the response of respondent at a single point. This limits the ability of design to observe the changes in an organization over time. Secondly, the research was conducted and data collected primarily based upon self-reported survey data from respondents through structured questionnaires. Although efforts were made to ensure objectivity and reliability of data collected, there remains a possibility of response biasness, where participants may have showed their organizations more positively. Finally, this study used a quantitative methods and statistical equation modelling through SmartPLS to analyses the relationships between different variables. While this approach provides healthy numerical evidence but does not capture qualitative aspects like organizational behaviors, individual perceptions, or contextual factors influencing risk management practices in pharmaceutical industry.

Researcher should consider a longitudinal approach which provides deeper understandings about CSF and how improvement in CSF influence risk management practices and organizational performance. Incorporating qualitative methods in research design such as interviews, focus groups, or case studies can provide deeper understandings into organizational behaviors, barriers, and success factors that quantitative data alone may not reveal. Comparative studies between different pharmaceutical industries locally and multinational pharmaceutical firms, or between different countries, could help to identify contextual differences in implementing effective risk management frameworks. Future research may also incorporate the role of digitalization, artificial intelligence, and data analytics in strengthening risk management system and compliance monitoring processes in pharmaceutical industries of Pakistan.

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