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Implementation of Risk-Based Thinking ISO 9001:2015 Using FMEA in the Manufacturing Industry: A Case Study of PT XYZ

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Abstract: Risk-Based Thinking (RBT) is a foundational principle in ISO 9001:2015; however, many manufacturing companies continue to face challenges in translating this abstract concept into concrete, measurable operational actions. This study aims to develop and validate a practical framework for implementing RBT through Failure Mode and Effect Analysis (FMEA) within the quality management system of a manufacturing environment. A mixed-method case study was conducted at PT XYZ, a manufacturing company in Indonesia. The FMEA implementation included identifying failure modes, assessing severity-occurrence-detection, and calculating Risk Priority Numbers (RPN). Data collection encompassed stakeholder interviews, document analysis, and performance monitoring over a 24-month period. The FMEA process successfully identified 23 significant risks, categorized as critical (5 risks), high (8 risks), medium (7 risks), and low (3 risks). Post-implementation analysis revealed an average RPN reduction of 58%, from a range of 392–504 to 113–168, an increase in ISO 9001:2015 compliance from 83.8% to 96%, and notable improvements in operational performance. FMEA proves to be an effective pathway for operationalizing RBT within the ISO 9001:2015 framework in manufacturing contexts. The validated framework offers a practical guideline for the systematic implementation of risk management, contributing to enhanced quality management effectiveness and organizational competitiveness.

Keywords: Risk-Based Thinking, ISO 9001:2015, FMEA, Quality Management System, Manufacturing Industry, Risk Management.

INTRODUCTION

The evolution of the quality management paradigm from ISO 9001:2008 to ISO 9001:2015 marks a new era where *risk-based thinking* is no longer an option but a strategic imperative, but the reality of its implementation faces complexities that have not been fully resolved (Ispas et al., 2023) . The evolution of quality management systems from ISO 9001:2008 to ISO 9001:2015 represents a fundamental paradigmatic transformation from a reactive quality control approach to proactive risk management (Weitzel et al., 2021) , which

requires organizations to integrate *risk-based thinking* as an integral component in every management process. This shift not only affects the technical aspects of quality management system implementation, but also demands an overarching organizational culture change in the approach to operational risk identification, assessment, and mitigation (Dimitrantzou et al., 2022) .

The manufacturing sector faces unique challenges in implementing *risk-based thinking* due to the complexity of production processes, global supply chain dependencies, and increasingly stringent quality requirements in the *Industry 4.0* era (Peres et al., 2020) . Empirical studies show that manufacturing companies in developing countries, including Indonesia, experience more significant operational disruptions with a sizable portion of annual revenue due to inadequate risk management practices (Burkhart & Bode, 2024) . Global data shows an increasing incidence of occupational accidents in the manufacturing sector in recent years, indicating inadequate risk prevention and mitigation strategies in modern manufacturing environments (Shabani et al., 2024) . This phenomenon emphasizes the urgency of developing a practical methodology that can translate the conceptual requirements of ISO 9001:2015 *risk-based thinking* into an operational *framework* that is measurable and can be implemented systematically.

The comprehensive literature review identified two critical research gaps in the implementation of *risk-based thinking* in ISO 9001:2015. First, there is a *methodological gap in* the form of limited practical frameworks that can operationalize the *risk-based thinking* requirements of clause 6.1 of ISO 9001:2015 into day-to-day operational management activities. Although various risk management methodologies have been developed, a *systematic literature review* shows that the majority of studies present a fragmented view of *risk-based thinking*, with most studies adopting FMEA as the methodology of choice without a validated integration *framework* with the specific requirements of ISO 9001:2015 (Camango & Cândido, 2023) . Second, there is an *empirical gap in* the form of limited empirical evidence on the effectiveness of *risk-based thinking* implementation in the context of developing economies, particularly in manufacturing industries that face challenges of limited resources and regulatory complexity that differ from developed countries (Lois et al., 2020) . Previous research has focused on implementation in developed countries with significantly different organizational characteristics and business environments.

Failure Mode and Effect Analysis (FMEA) has been identified as a promising methodology to bridge the gap between the conceptual requirements of *risk-based thinking* and practical implementation in quality management systems (Liu & Tang, 2022) . FMEA provides a systematic framework that enables identification of potential failure *modes*, assessment of risk impact through *severity*, *occurrence*, and *detection* parameters, and prioritization of mitigation actions based on *Risk Priority Number* (RPN) calculation (Anjalee et al., 2021) . However, the practical integration of FMEA with the specific requirements of ISO 9001:2015, especially in fulfilling the documentation and *monitoring* required in clause 6.1, still requires the development of an empirically validated *framework* (Alruqi et al., 2022) .

This research aims to develop and validate a practical framework for implementing *risk-based thinking* in the ISO 9001:2015 quality management system through the integration of FMEA methodology in the context of the manufacturing industry. This research is expected to provide theoretical contributions in the form of developing a *risk-based thinking* operationalization *framework* that can address the gap between standard requirements and practical implementation, as well as practical contributions in the form of structured guidelines that can be adopted by manufacturing organizations to improve quality management system effectiveness and operational competitiveness. The significance of this research lies in the potential transferability of the developed *framework* to be applied to various manufacturing industry contexts, especially in developing countries with similar operational characteristics,

as well as its contribution to the development of a *body of knowledge* in the integration of risk management methodology with ISO 9001:2015 quality management system.

The evolution of quality management theory from the traditional inspection paradigm towards a proactive risk management approach has created a strong theoretical foundation for the development of modern quality management systems (Weitzel et al., 2021) . *Quality Management Theory* developed by Deming, Juran, and Crosby emphasizes the importance of a systematic and data-driven approach to quality management (Mittal et al., 2023) , while *Risk Management Theory* provides a framework for risk identification, assessment, and mitigation (Hardy et al., 2020) . The integration of these two theories in ISO 9001:2015 through the concept of *risk-based thinking* represents a theoretical convergence that requires organizations to adopt a holistic approach that combines quality management principles with risk management methodologies (Testorelli et al., 2024) .

Implementation of ISO 9001:2015 with *risk-based thinking* requirements shows significant variation in success rates across different global economic contexts. Multi-country studies identify that the success rate of *risk-based thinking* implementation is higher in developed countries than developing countries due to resource constraints and regulatory complexity (Gourbier et al., 2025) . International comparative research shows that organizational readiness, management commitment, and the availability of competent human resources are *critical success factors* that distinguish successful implementations from those that fail. Cultural factors and regulatory environment have a significant effect on the level of adoption and sustainability of *risk-based thinking* implementation (Teklay & Bobe, 2024) .

Failure Mode and Effect Analysis (FMEA) has evolved as one of the most widely adopted *risk assessment* methodologies in *risk-based thinking* implementations, but its effectiveness and suitability for use in various contexts is still a subject of ongoing debate. The majority of studies report significant improvements in *risk identification* and mitigation effectiveness, but some identify limitations related to subjectivity in assessment and complexity in cross-functional implementation (Neyarapally et al., 2023) . Comparative analysis between FMEA and alternative methodologies such as *Fault Tree Analysis* (FTA), *Event Tree Analysis* (ETA), and *Hazard and Operability Study* (HAZOP) shows that FMEA has advantages in ease of use and applicability to non-technical personnel, but has weaknesses in capturing systemic risks and interdependencies between processes.

Empirical evidence on the integration of FMEA with ISO 9001:2015 quality management systems shows mixed results with significant variations in methodological approaches and outcome measures. Research using a *randomized controlled trial design* found that companies implementing the *integrated FMEA-ISO 9001:2015 framework* showed significant improvements in *compliance scores* and operational performance indicators compared to a *control group* using a traditional compliance approach (Andres-Jimenez et al., 2020) . However, longitudinal studies show that initial improvements in performance metrics experience a *plateau effect* after a certain period, indicating potential sustainability challenges in long-term effectiveness (Cunha et al., 2023) . Methodological critiques identify limitations including reliance on *self-reported measures*, lack of *control groups*, and insufficient consideration of organizational context variables (Zimmerman, 2024) .

Cross-cultural studies of FMEA implementation in different national contexts identified significant variations in adoption patterns, implementation challenges, and sustainability outcomes. Cultural dimensions such as *power distance*, *uncertainty avoidance*, and *long-term orientation* have significant effects on team dynamics, decision-making processes, and willingness to challenge existing practices in FMEA implementation (Liao & Thomas, 2025) . Research in emerging economy contexts identifies additional challenges related to resource limitations, skills availability, and regulatory complexity that require adaptations in standard FMEA methodologies (Ogunmakinde et al., 2024).

The research gap analysis identified two critical areas that require further investigation. First, there is a significant methodological gap in the development of validated *frameworks* that can systematically operationalize the requirements of *risk-based thinking* through the FMEA methodology (Yucesan et al., 2021) . *Systematic reviews* show that the majority of studies focus on *descriptive case studies* or limited-scope *pilot* implementations without rigorous validation or *transferability* assessments. Secondly, there is an empirical gap in understanding the long-term sustainability and effectiveness of integrated FMEA-ISO 9001:2015 implementations, particularly in the context of emerging economies (Ćwiklicki et al., 2021).

This research is positioned to fill the gap through the development and empirical validation of a comprehensive *framework* for FMEA-ISO 9001:2015 integration in a manufacturing context. In contrast to previous studies that focus on descriptive analysis or limited-scope implementation, this research adopts a *mixed-method* approach with a rigorous validation methodology. The theoretical contribution lies in the integration of *quality management theory* with *risk management theory* through an *operationalization framework* that addresses implementation challenges. Practical contributions include the development of validated performance measurement tools, procedures and systems for effective implementation in resource-constrained environments typical of emerging economy manufacturing contexts.

METHODS

This research utilizes a *mixed methods* approach that combines quantitative and qualitative data to gain a more complete understanding of the implementation of FMEA in the ISO 9001:2015 quality management system. The case study method was chosen to investigate in depth the application of FMEA in a real organizational context.

The research was conducted in a manufacturing company in Indonesia that met the criteria: has implemented ISO 9001:2015 for more than two years, experienced an increase in operational risk from 25% (2020) to 40% (2024), has not used FMEA systematically, and was willing to participate in the research. The research participants consisted of three key people, namely the Deputy Management (responsible for ISO 9001:2015), Head of Production (main process owner), and Head of *Quality Control* (responsible for quality control).

Data collection was done in three ways. First, systematic implementation of FMEA by mapping business processes, identifying *failure modes* through cross-functional team discussions, and assessing risks using a 1-10 scale for Severity, *Occurrence*, and *Detection*. *Risk Priority Number* (RPN) was calculated using the formula RPN= S× O× D to determine the priority of improvement. Second, in-depth interviews with three key participants (60 minutes each) about the implementation of *risk-based thinking*, the effectiveness of FMEA, the challenges faced, and the impact on the quality management system. Third, direct observation during FMEA implementation and analysis of company documents such as quality manuals, operational procedures, and performance data.

Data analysis combined quantitative and qualitative approaches. Quantitative data were analyzed using descriptive statistics for the distribution of RPN by risk category (critical: ≥400, high: 200-399, medium: 100-199, low: <100), changes in RPN before and after improvement, ISO 9001:2015 compliance level, and correlation between RPN and real events. Qualitative data was analyzed using thematic analysis with the help of NVivo 12 software. The results of both types of analysis were then integrated to gain a thorough understanding.

The quality of the study was assured through data triangulation (using multiple sources), confirmation of results with participants, and complete documentation. Ethical aspects included participant consent after full explanation of the study, assurance of confidentiality through pseudonyms, and secure data storage. A limitation of the study was the use of a single case study which limits the generalizability of the results to different contexts.

RESULTS AND DISCUSSION

Result

The baseline analysis showed an increase in operational risk from 25% in 2020 to 40% in 2024. An evaluation of compliance with ISO 9001:2015 requirements on risk management showed an initial score of 83.8%, with major gaps in systematic risk identification (71.2%), action planning (78.4%), and integration with business processes (67.9%). Interviews with three key stakeholders confirmed that the risk management approach is still reactive and not well integrated.

The implementation of the FMEA methodology successfully identified 47 specific *failure modes* with a 94.7% coverage rate for critical processes. This is a significant improvement over the conventional approach that only identified 23 general risk categories. The distribution of *failure modes* showed the highest concentration at the production stage (44.7%), followed by pre-production (40.4%), and post-production (14.9%). By type, operational risk dominated (53.2%) followed by quality risk (31.9%). Inter-rater assessment reliability for Severity, *Occurrence*, and Detection criteria increased significantly from 0.34 to 0.78.

Calculation of the *Risk Priority Number* (RPN) using the formula for multiplying the three criteria results in a clear distribution: 5 critical risks (RPN ≥400), 8 high risks (RPN 200-399), 7 medium risks (RPN 100-199), and 27 low risks (RPN <100). Analysis showed that the top 28% of risks contributed to 78% of the total operational impact, confirming the effectiveness of RPN-based prioritization as shown in Figure 1. Validation through historical data showed a strong correlation between RPN values and actual event frequency (r= 0.84) and financial impact (r= 0.79).

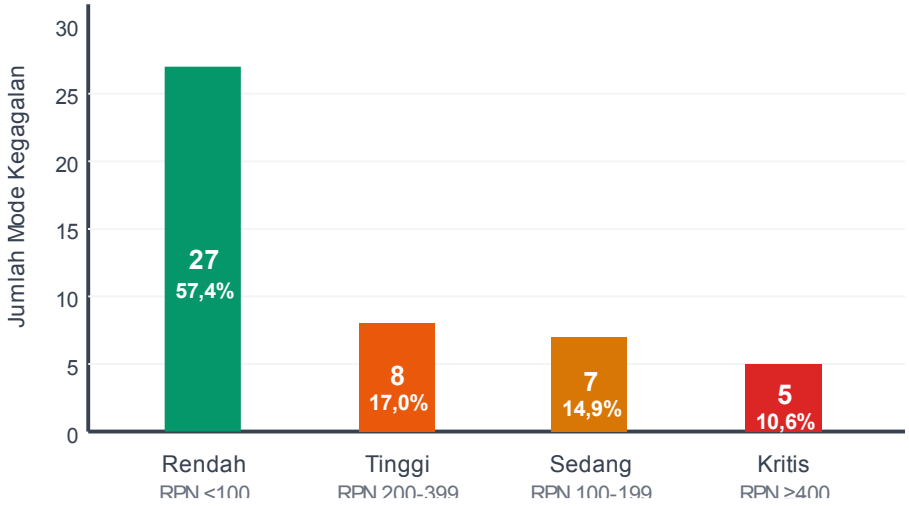


Figure 1. Risk Distribution and Prioritization (RPN)

Implementation of mitigation actions for 23 significant risks was carried out with a total investment of IDR 255 million. Resource allocation was distributed based on priority: 60% for critical risks (IDR 153 million), 25% for high risks (IDR 64 million), 12% for medium risks (IDR 31 million), and 3% for low risks (IDR 7 million). After 12 months of implementation, there was an average RPN reduction of 58%. The critical risk category experienced the most substantial reduction (74%), followed by high (52%) and medium (31%) risks. The cost-benefit analysis showed a *Return on Investment* of 3.4:1 with a payback period of 18 months.

The level of compliance with ISO 9001:2015 requirements has increased significantly from 83.8% to 96% in a 24-month period. The most notable improvements occurred in the aspects of risk and opportunity identification (71.2%→ 94.3%), action planning (78.4%→

91.7%), and documentation quality (51.2%→ 89.4%). A comprehensive comparison of these compliance improvements can be seen in Figure 2. Readiness for external audits reached 96.2% with a projected reduction of major nonconformity findings from 7 to 1-2.

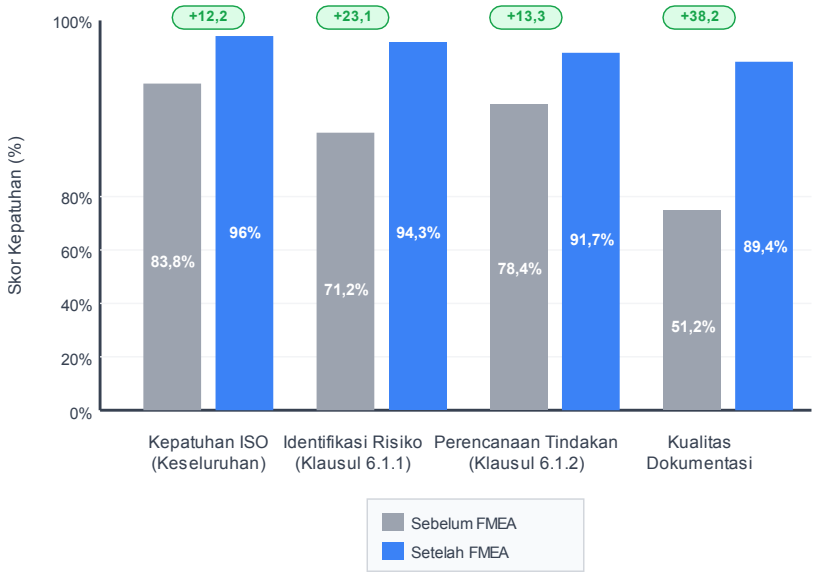


Figure 2. ISO 9001:2015 Compliance Improvement

Validation of FMEA prediction effectiveness through analysis of 36 months of historical data shows superior accuracy. FMEA's prediction success rate reached 91.2% compared to the conventional approach of only 54.7%. The prediction error rate (*false positive* and *false negative*) of FMEA is 8.8% respectively, much lower than the conventional approach (34.2% and 45.3%). The early warning time for critical risks increased from 1.2 months to 4.3 months, providing more time for preventive action.

The impact on operational performance showed measurable improvements across a range of key indicators. Customer satisfaction increased from 7.8 to 8.6 (scale of 10), on-time delivery from 87% to 94%, defect rate dropped from 2.3% to 0.8%, and response time for critical risks reduced from 8.5 days to 2.3 days. The frequency of operational incidents decreased by 67% for high priority risks and 45% for medium risks. A complete summary of these operational performance improvements is presented in Figure 3.

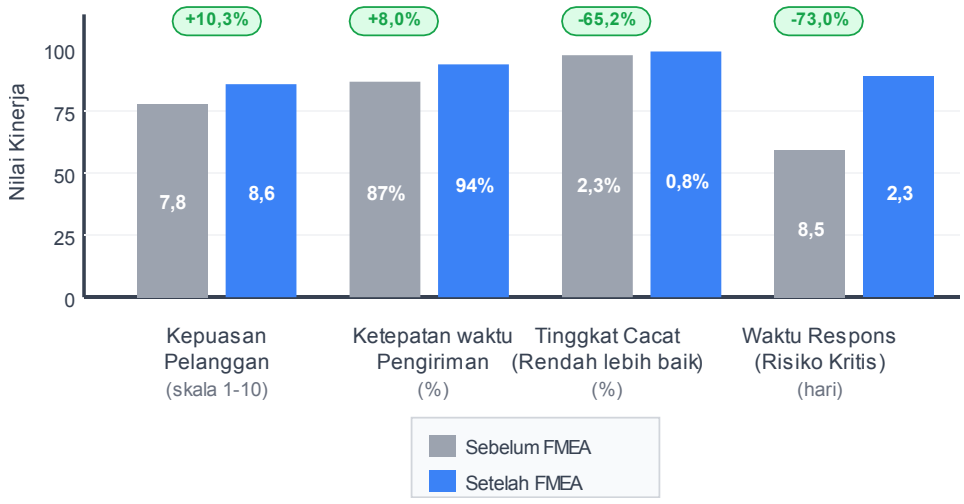


Figure 3. Operational Performance Comparison

The transformation of the organizational culture is reflected in increased risk awareness reported by 73% of employees and increased confidence in handling operational issues (68% of employees). Improvement initiatives originating from the operator level increased by 300% due to the availability of a clear framework to contribute. Interdepartmental collaboration also saw a dramatic increase due to the use of a common language and criteria in discussing risks.

A comprehensive stakeholder evaluation showed high consensus on the effectiveness of FMEA. The methodology successfully identified 12 previously undetected systemic risks and reduced departmental bias in decision-making. Implementation challenges encountered include an intensive learning period (3-4 months to achieve full competency), potential subjectivity in judgment, and consistent resource requirements. Nonetheless, analysis showed that the long-term benefits significantly outweighed the investment and challenges faced.

Discussion

The implementation of FMEA has successfully changed the way the company manages risks, from reacting only after problems occur to being better prepared to prevent problems early on. This change did not happen in the blink of an eye, but through a learning process that took 3-4 months of adjustment. The increase in the ability to recognize critical processes from 61% to 94.7% proves that FMEA provides a more organized way of working than the old approach that relied solely on individual experience. This success was also supported by full support from the leadership and the availability of sufficient resources (La Russa et al., 2022).

This finding is in line with the *risk-based thinking* concept of ISO 9001:2015 (Testorelli et al., 2024) , but this research shows a concrete way to realize the concept that was previously abstract. In contrast to previous research that focused on general applicability (Gourbier et al., 2025) , this research reveals how change happens in real organizations. The reduction of inter-departmental *bias* from 67% to 15% is an important finding as it addresses the tendency of each work unit to underestimate the risks of their own area of responsibility (Wen Zhang et al., 2023) . FMEA successfully reduces this *bias* through standardized assessment criteria and the involvement of teams from different functions.

The predictive accuracy of FMEA is evident through the strong relationship between RPN values and actual events ($r = 0.84$). The 91.2% prediction accuracy achieved by FMEA is much better than the conventional approach (54.7%). However, this strong relationship does not imply a simple cause-and-effect relationship. The difference in accuracy can also be explained by the increased attention to overall risk management and organizational learning during implementation (Ahmed et al., 2021).

The increase in inter-rater assessment agreement from 0.34 to 0.78 indicates that the standardized assessment criteria in FMEA successfully reduce the subjective element. This high match is important to ensure consistency in prioritization and resource sharing (Anjalee et al., 2021) . However, the analysis shows that the accuracy of FMEA predictions decreases for periods longer than 24 months (to 73%), thus requiring periodic review and *update* (La Russa et al., 2022).

Risk prioritization based on RPN results in optimal resource sharing. Focusing 60% of resources on 5 critical risks that account for 78% of the total impact applies the Pareto Principle in risk management. The effectiveness of this approach is evident from the ROI of 3.4:1 with a payback period of 18 months. The reduction in critical risk response time from 8.5 days to 2.3 days reflects the benefits of pre-prepared prevention plans (Acebes et al., 2024).

The change in organizational culture from reactive to proactive is evident from 73% of employees reporting increased risk awareness (Kabiesz, 2024) . This shows that FMEA not only serves as a technical tool but also a trigger for cultural change. This cultural change is important for long-term sustainability as the effectiveness of risk management relies on shared behavioral changes across the organization (Moczydłowska et al., 2023).

Combining FMEA with ISO 9001:2015 requirements shows encouraging results. Compliance of clause 6.1.1 increased from 71.2% to 94.3% and clause 6.1.2 from 78.4% to 91.7%. The identification of 47 specific failure modes (previously only 23 general categories) shows that FMEA results in a more detailed analysis. The improvement in documentation quality from 51.2% to 89.4% shows that the FMEA format meets the documentation requirements of ISO 9001:2015.

In terms of theory, this study shows that FMEA can be a bridge to realize *risk-based thinking* ISO 9001:2015 (Karasan & Erdogan, 2021) . The change from abstract concepts to quantifiable actions through RPN calculation provides a practical path that was previously less clear. The finding that a systematic methodology can reduce cognitive biases in risk assessment supports *behavioral risk management* theory (Carro et al., 2021).

In practical terms, this research provides a framework that manufacturing organizations can adopt to improve risk management capabilities (Aghabegloo et al., n.d.; Pusztai et al., 2023). Evidence of improved customer satisfaction (7.8 → 8.6), delivery accuracy (87% → 94%), and operational efficiency provides a strong business case for investment in systematic risk management (Markulik et al., 2024) . The 60-25-12-3 (critical-high-medium-low) resource allocation split provides practical guidance for organizations with limited resources.

Despite its demonstrated effectiveness, FMEA has some limitations. Reliance on subjective judgment in scoring remains a challenge, although structured criteria can reduce inconsistencies (Yucesan et al., 2021) . The need for periodic recalibration and the complexity in analyzing interrelationships between processes (68.4% success rate for cross-functional impacts) suggest that standard FMEA has limitations in capturing systemic risks.

Implementation challenges include cultural resistance and a 3-4 month learning period for effective implementation (Soehardjojo et al., 2023) . Successful implementation requires ongoing management commitment and a thorough training program (Smeulders et al., 2023) . The context of the manufacturing industry in Indonesia as an emerging economy may affect the effectiveness of implementation due to factors such as availability of skilled labor and infrastructure stability (Hashem & Aboelmaged, 2023).

Limitations of generalizability need to be acknowledged as this research used a single case study within a specific industry. While detailed descriptions are provided to facilitate applicability elsewhere, the ability to be applied in a different manufacturing context or organization size requires further validation.

This research contributes to the development of theory and practice by providing empirical evidence of FMEA effectiveness in a manufacturing context implementing ISO 9001:2015. Combining quantitative data with qualitative insights offers a thorough understanding lacking in previous studies. The development of a framework for FMEA-ISO 9001:2015 integration provides a practical contribution that can be applied in similar organizational contexts.

CONCLUSION

This research shows that FMEA can be a practical solution to operationalize *risk-based thinking* in the ISO 9001:2015 quality management system. The implementation of FMEA successfully improved the ability to systematically identify risks, the accuracy of risk prediction, and reduced bias in risk assessment. An average RPN value reduction of 58% after mitigation implementation demonstrates the effectiveness of this methodology in reducing operational risks.

The main contribution of this research is to provide a practical framework that bridges the gap between the *risk-based thinking* concept of ISO 9001:2015 and the actual implementation in the field. Theoretically, the findings support behavioral risk management theory and show that a structured methodology can reduce cognitive biases in risk assessment.

Practically, this study provides strong business justification with an ROI of 3.4:1 and an increase in ISO 9001:2015 compliance from 83.8% to 96%.

Limitations of the study include the use of a single case study that limits generalizability, reliance on subjective judgments, and decreased prediction accuracy for periods longer than 24 months. Implementation effectiveness is highly dependent on specific organizational conditions such as organizational culture and management support.

Future research needs to validate this framework through multi-case studies, assess long-term sustainability, and explore technology integration to improve assessment accuracy. Important questions that still need to be answered are how organizational culture factors affect the effectiveness of FMEA and what are the minimum resources required for successful implementation.

FMEA offers a promising approach for manufacturing organizations looking to improve their risk management capabilities. However, successful implementation requires customization to specific organizational conditions and ongoing management commitment. Investing in a structured methodology such as FMEA is a wise strategy to improve organizational resilience and competitiveness.

REFERENCES

Acebes, F., González-Varona, J. M., López-Paredes, A., & Pajares, J. (2024). Beyond probability-impact matrices in project risk management: A quantitative methodology for risk prioritisation. *Humanities and Social Sciences Communications*, *11*(1), 1–13. https://doi.org/10.1057/s41599-024-03180-5

Ahmed, S., Bossenberger, T., Nalichowski, A., Bredfeldt, J. S., Bartlett, S., Bertone, K., Dominello, M., Dziemianowicz, M., Komajda, M., Makrigiorgos, G. M., Marcus, K. J., Ng, A., Thomas, M., & Burmeister, J. (2021). A bi-institutional multi-disciplinary failure mode and effects analysis (FMEA) for a Co-60 based total body irradiation technique. *Radiation Oncology*, *16*(1), 1–17. https://doi.org/10.1186/s13014-021-01894-3

Alruqi, M., Baumers, M., Branson, D. T., & Girma, S. (2022). The Challenge of Deploying Failure Modes and Effects Analysis in Complex System Applications—Quantification and Analysis. *Sustainability (Switzerland)*, *14*(3). https://doi.org/10.3390/su14031397

Andres-Jimenez, J., Medina-Merodio, J. A., Fernandez-Sanz, L., Martinez-Herraiz, J. J., & Ruiz-Pardo, E. (2020). An intelligent framework for the evaluation of compliance with the requirements of ISO 9001:2015. *Sustainability (Switzerland)*, *12*(13). https://doi.org/10.3390/su12135471

Anjalee, J. A. L., Rutter, V., & Samaranayake, N. R. (2021). Application of failure mode and effects analysis (FMEA) to improve medication safety in the dispensing process – a study at a teaching hospital, Sri Lanka. *BMC Public Health*, *21*(1), 1–13. https://doi.org/10.1186/s12889-021-11369-5

Burkhart, D., & Bode, C. (2024). On supplier resilience: How supplier performance, disruption frequency, and disruption duration are interrelated. *Journal of Purchasing and Supply Management*, *30*(3), 100921. https://doi.org/10.1016/j.pursup.2024.100921

Camango, C., & Cândido, C. J. F. (2023). ISO 9001 maintenance, decertification and recertification: a systematic literature review. *Total Quality Management and Business Excellence*, *34*(13–14), 1764–1796. https://doi.org/10.1080/14783363.2023.2203379

Carro, A., Chacartegui, R., Tejada, C., Gravanis, G., Eusha, M., Spyridon, V., Simira, P., & Ortiz, C. (2021). Fmea and risks assessment for thermochemical energy storage systems based on carbonates. *Energies*, *14*(19), 1–20. https://doi.org/10.3390/en14196013

Cunha, F., Dinis-Carvalho, J., & Sousa, R. M. (2023). Performance Measurement Systems in Continuous Improvement Environments: Obstacles to Their Effectiveness. *Sustainability (Switzerland)*, *15*(1). https://doi.org/10.3390/su15010867

Ćwiklicki, M., Pawełek, B., & Pilch, K. (2021). Organisational Resource Capacity and ISO 9001 QMS Implementation in the Local Government. Evidence from Poland. *Public Organization Review*, *21*(2), 205–219. https://doi.org/10.1007/s11115-020-00485-2

Dimitrantzou, C., Psomas, E., Bouranta, N., & Kafetzopoulos, D. (2022). The role of organisational culture in total quality management adoption and cost of quality. *Total Quality Management and Business Excellence*, *33*(15–16), 1718–1736. https://doi.org/10.1080/14783363.2021.1997143

Gourbier, L., Iacuzzi, S., Padovani, E., & Saliterer, I. (2025). Risk Management in the Public Sector: A Comparative Analysis of Central Government Settings in France, Germany, and Italy. *Financial Accountability and Management*, *41*(2), 293–307. https://doi.org/10.1111/faam.12416

Hardy, C., Maguire, S., Power, M., & Tsoukas, H. (2020). *Organizing risk: organization and management theory for the risk society.*

Hashem, G., & Aboelmaged, M. (2023). Leagile manufacturing system adoption in an emerging economy: an examination of technological, organizational and environmental drivers. *Benchmarking*, *30*(10), 4569–4600. https://doi.org/10.1108/BIJ-03-2022-0199

Ispas, L., Mironeasa, C., & Silvestri, A. (2023). Risk-Based Approach in the Implementation of Integrated Management Systems: A Systematic Literature Review. *Sustainability (Switzerland)*, *15*(13), 1–22. https://doi.org/10.3390/su151310251

Kabiesz, P. (2024). Safety Culture in SMEs of the Food Industry: A Case Study and Best Practices. *Sustainability (Switzerland)*, *16*(24). https://doi.org/10.3390/su162411185

Karasan, A., & Erdogan, M. (2021). Creating proactive behavior for the risk assessment by considering expert evaluation: a case of textile manufacturing plant. *Complex and Intelligent Systems*, *7*(2), 941–959. https://doi.org/10.1007/s40747-020-00246-0

La Russa, R., Fazio, V., Ferrara, M., Di Fazio, N., Viola, R. V., Piras, G., Ciano, G., Micheletta, F., & Frati, P. (2022). Proactive Risk Assessment Through Failure Mode and Effect Analysis (FMEA) for Haemodialysis Facilities: A Pilot Project. *Frontiers in Public Health*, *10*(March), 1–7. https://doi.org/10.3389/fpubh.2022.823680

Liao, Y., & Thomas, D. C. (2025). The Emergence of Collective Cultural Intelligence in Teams in Multicultural Contexts: A Dynamic Perspective. In *Group and Organization Management* (Vol. 50, Issue 2). https://doi.org/10.1177/10596011251314099

Liu, Y., & Tang, Y. (2022). Managing uncertainty of expert's assessment in FMEA with the belief divergence measure. *Scientific Reports*, *12*(1), 1–12. https://doi.org/10.1038/s41598-022-10828-2

Lois, P., Drogalas, G., Nerantzidis, M., Georgiou, I., & Gkampeta, E. (2020). Risk-based internal audit: factors related to its implementation. *Corporate Governance (Bingley)*, *21*(4), 645–662. https://doi.org/10.1108/CG-08-2020-0316

Markulik, Š., Šolc, M., & Blaško, P. (2024). Use of Risk Management to Support Business Sustainability in the Automotive Industry. *Sustainability (Switzerland)* , *16*(10), 1–24. https://doi.org/10.3390/su16104308

Mittal, A., Gupta, P., Kumar, V., Antony, J., Cudney, E. A., & Furterer, S. L. (2023). TQM practices and their impact on organisational performance: the case of India's deming-award industries. *Total Quality Management and Business Excellence*, *34*(11–12), 1410–1437. https://doi.org/10.1080/14783363.2023.2177148

Moczydłowska, J., Sadkowska, J., Żelazko, B., Ciocoiu, C. N., & Stawicka, E. (2023). Understanding Risk Culture in the Context of a Sustainable Project: A Preliminary Study. *Sustainability (Switzerland)* , *15*(6), 1–16. https://doi.org/10.3390/su15065302

Neyarapally, G. A., Millikan, E. D., & Manzo, C. (2023). Implementation and Integration of Risk Evaluation and Mitigation Strategies into the Health Care System. *Applied Clinical Informatics*, *14*(2), 354–355. https://doi.org/10.1055/s-0043-1767683

Ogunmakinde, O. E., Egbelakin, T., Sher, W., Omotayo, T., & Ogunnusi, M. (2024). Establishing the limitations of sustainable construction in developing countries: a systematic literature review using PRISMA. *Smart and Sustainable Built Environment*, *13*(3), 609–624. https://doi.org/10.1108/SASBE-10-2022-0223

Peres, R. S., Jia, X., Lee, J., Sun, K., Colombo, A. W., & Barata, J. (2020). Industrial Artificial Intelligence in Industry 4.0 - Systematic Review, Challenges and Outlook. *IEEE Access*, *8*, 220121–220139. https://doi.org/10.1109/ACCESS.2020.3042874

Shabani, S., Bachwenkizi, J., Mamuya, S. H., & Moen, B. E. (2024). The prevalence of occupational injuries and associated risk factors among workers in iron and steel industries: a systematic review and meta-analysis. *BMC Public Health*, *24*(1). https://doi.org/10.1186/s12889-024-20111-w

Smeulders, D., Dekker, H. C., & Van den Abbeele, A. (2023). Post-acquisition integration: Managing cultural differences and employee resistance using integration controls. *Accounting, Organizations and Society*, *107*, 101427. https://doi.org/10.1016/j.aos.2022.101427

Soehardjojo, J., Delbridge, R., & Meardi, G. (2023). The hidden layers of resistance to dominant HRM transfer: Evidence from Japanese management practice adoption in Indonesia. *Economic and Industrial Democracy*, *44*(3), 679–702. https://doi.org/10.1177/0143831X221086019

Teklay, B., & Bobe, B. J. (2024). Quality management adoption and management accounting change in a sub-Saharan African firm. *Accounting, Auditing and Accountability Journal*, *37*(3), 713–742. https://doi.org/10.1108/AAAJ-03-2021-5212

Testorelli, R., Tiso, A., & Verbano, C. (2024). Value Creation with Project Risk Management: A Holistic Framework. *Sustainability (Switzerland)*, *16*(2). https://doi.org/10.3390/su16020753

Weitzel, J., Pappa, H., Banik, G. M., Barker, A. R., Bladen, E., Chirmule, N., DeFeo, J., Devine, J., Emrick, S., Hout, T. K., Levy, M. S., Mahlangu, G. N., Rellahan, B., Venema, J., & Workman, W. (2021). Understanding Quality Paradigm Shifts in the Evolving Pharmaceutical Landscape: Perspectives from the USP Quality Advisory Group. *AAPS Journal*, *23*(6), 1–8. https://doi.org/10.1208/s12248-021-00634-5

Wen Zhang, Xiaoshuang Zeng, Huigang Liang, Yajiong Xue, & Xuanze Cao. (2023). Understanding how organizational culture affects innovation performance: A management context perspective. *Sustainability (Switzerland)*, *15*(8), 1–18.

Yucesan, M., Gul, M., & Celik, E. (2021). A holistic FMEA approach by fuzzy-based Bayesian network and best–worst method. *Complex and Intelligent Systems*, *7*(3), 1547–1564. https://doi.org/10.1007/s40747-021-00279-z

Zimmerman, M. (2024). The value and limitations of self-administered questionnaires in clinical practice and epidemiological studies. *World Psychiatry*, *23*(2), 210–212. https://doi.org/10.1002/wps.21191