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The Role of Quality and Safety Management in the Transformations of the Fourth Industrial Revolution: A Structural Equation Modeling Approach

ABSTRACT

This study aims to examine the impact of quality management and safety management practices on industrial transformation within the context of the Fourth Industrial Revolution (Industry 4.0). A quantitative survey design was applied among managers of Daqiq Farayand Khavarmiane Company, representing industrial organizations transitioning to Industry 4.0. A standard questionnaire was used to measure key variables related to quality and safety management. Its content validity was verified by expert evaluation using CVR and CVI indices, and reliability was confirmed with Cronbach's alpha values above 0.80. Data were collected through simple random sampling, resulting in 380 valid responses. The normality of data was checked via the Kolmogorov–Smirnov test, and due to non-normal distribution, Partial Least Squares Structural Equation Modeling (PLS-SEM) was employed for hypothesis testing and path analysis using SmartPLS software. Model evaluation indicated strong convergent validity with factor loadings above 0.60 and significant path coefficients between quality management, safety management, and industrial transformation. All hypothesized relationships were confirmed as positive and statistically significant at the 95% confidence level, with t-values exceeding 1.96. The results demonstrated that enhanced quality and proactive safety systems strongly influence successful industrial process transformation and adaptation to Industry 4.0 technologies. The findings highlight the pivotal role of integrated quality and safety management in supporting industrial digital transformation during the Fourth Industrial Revolution. By leveraging advanced technologies such as artificial intelligence, IoT, and smart monitoring systems, organizations can achieve continuous improvement, strengthen risk management, and accelerate innovation. Developing digital competencies and fostering a strong culture of safety and quality are essential for competitive sustainability in rapidly evolving technological environments.

Keywords: Industry 4.0; quality management; safety management; structural equation modeling; digital transformation; artificial intelligence; smart monitoring systems

Introduction

The Fourth Industrial Revolution (Industry 4.0) represents an unprecedented convergence of physical, digital, and cyber-physical systems that is reshaping manufacturing and service industries across the globe. Unlike previous industrial transformations that primarily focused on mechanization, electrification, or digitalization, Industry 4.0 integrates smart technologies such as the Internet of Things (IoT), big data analytics, artificial intelligence (AI), robotics, and cyber-physical systems into production and management processes [1, 2]. This integration has enabled real-time decision-making, predictive analytics, and adaptive process control while significantly influencing quality assurance and safety practices [3, 4]. With these

advancements, organizations face both opportunities and complexities, including the need to redesign traditional management systems to remain competitive and ensure workplace safety and quality performance [5].

One of the most notable changes is the evolution of quality management toward the concept of “Quality 4.0,” which aligns traditional total quality management (TQM) principles with digital enablers to ensure process excellence in an interconnected environment [1]. Quality 4.0 leverages digital technologies to move beyond static inspection and reactive measures, enabling predictive quality control and continuous improvement supported by data-driven insights [5, 6]. AI, machine learning algorithms, and IoT sensors can now predict deviations and failures before they impact production, improving overall equipment effectiveness and reducing costs [2, 7]. The result is a paradigm shift where quality management becomes proactive, self-learning, and deeply integrated into digital platforms [8].

Parallel to the transformation of quality systems, safety management has undergone significant modernization through the adoption of Industry 4.0 technologies. Conventional occupational health and safety (OHS) frameworks, which rely on lagging indicators and manual audits, are no longer sufficient in highly automated and data-driven environments [9]. Smart safety management systems now use IoT-enabled sensors, wearable devices, and AI-based analytics to monitor environmental conditions and human interactions with machinery in real-time [10, 11]. These digital solutions make it possible to detect hazardous conditions, predict accidents, and trigger automated safety responses to minimize risks [3, 4]. Moreover, integrating predictive analytics into safety management fosters a proactive safety culture and reduces workplace incidents [7, 12].

The convergence of quality and safety management under the Industry 4.0 framework has broad strategic implications. Organizations are now expected to embed continuous monitoring, data-driven insights, and agile responses into their operational models [1, 8]. Quality assurance no longer functions as an isolated department but interacts dynamically with production, maintenance, and supply chain functions through shared digital platforms [2]. Similarly, safety management is shifting from reactive compliance to predictive and prescriptive approaches that support resilient operations and employee well-being [9, 13]. These changes not only reduce operational disruptions but also support organizational sustainability and competitive advantage [6, 14].

Industry 4.0's potential to revolutionize quality and safety is accompanied by significant implementation challenges. Organizations must contend with technological complexity, integration issues, and skill shortages [15, 16]. Small and medium-sized enterprises (SMEs) in particular face barriers related to digital readiness, investment capacity, and cybersecurity risks [17, 18]. Resistance to change, unclear return on investment, and inadequate digital infrastructure further hinder the widespread adoption of advanced quality and safety systems [16, 19]. Moreover, as automation and AI reshape jobs and tasks, organizations must navigate workforce transitions to maintain both productivity and employee well-being [13, 14].

Another emerging issue is the governance and ethical dimension of data-driven quality and safety management. Continuous monitoring through sensors and AI can enhance safety and performance but may also raise concerns about data privacy and surveillance [12, 13]. Ethical frameworks and regulatory compliance need to evolve to support digital transformation while safeguarding workers' rights and trust [10, 11]. Balancing technological adoption with ethical and legal considerations is thus critical for sustainable digitalization strategies [8, 9].

Despite these challenges, the integration of Industry 4.0 technologies into quality and safety management offers a strategic pathway to operational excellence and competitive advantage. Digital platforms such as advanced analytics, cyber-

physical systems, and AI-driven decision support can help organizations achieve higher levels of precision, agility, and resilience [1, 5]. Real-time feedback loops allow for adaptive control of processes, while predictive models anticipate defects, risks, and equipment failures [2, 7]. These capabilities support not only cost reduction but also enhanced value creation through improved product reliability, reduced downtime, and safer workplaces [3, 4].

To fully capitalize on these opportunities, leadership commitment and workforce upskilling are vital. Organizations must foster digital literacy among managers and frontline workers to effectively utilize advanced safety and quality tools [6, 8]. Cross-functional collaboration, agile organizational structures, and investment in digital infrastructure form the backbone of successful implementation [20, 21]. Training programs, change management strategies, and incentives that encourage data-driven decision-making can also facilitate cultural transformation [15, 18].

Additionally, research suggests that adopting a systemic approach by combining Industry 4.0 technologies with sustainability and circular economy principles can multiply benefits [17, 18]. For example, using IoT and AI for predictive maintenance reduces resource consumption and waste while enhancing safety and quality [2, 4]. Data-driven insights also enable continuous improvement aligned with environmental and social responsibility goals, reinforcing corporate reputation and stakeholder trust [1, 6].

The growing body of literature emphasizes the need for integrated models that combine advanced technologies with robust management frameworks to guide organizations through digital transformation [5, 8]. Such models can help managers evaluate readiness levels, identify capability gaps, and prioritize investments in technologies that yield the greatest impact on both quality and safety [10, 11]. They also support strategic decision-making by clarifying the interdependencies between digital enablers, workforce competence, and organizational performance [3, 9].

Given these theoretical and practical considerations, this study investigates how quality and safety management systems influence industrial transformation in the era of Industry 4.0.

Methodology

This research adopted an applied, quantitative survey design aimed at investigating the role of quality and safety management in the context of the Fourth Industrial Revolution. The statistical population comprised managers of Daqiq Farayand Khavarmiane Company, an industrial organization experiencing digital transformation and the integration of smart technologies. Because the target population was not fully listed and direct access to all members was challenging, simple random sampling was selected as an appropriate and unbiased approach. The sample size was determined using the infinite population formula with a 95% confidence level and an assumed standard deviation of 0.5, resulting in a calculated sample of 384 participants. After adjusting for data quality and non-response, 380 completed and valid questionnaires were analyzed. This sampling strategy ensured adequate representativeness of the target population and provided sufficient statistical power for structural equation modeling.

The primary data collection instrument was a structured and standardized questionnaire developed based on the research conceptual model and prior validated instruments in the field of quality and safety management within Industry 4.0 environments. The tool consisted of three sections: demographic information (gender, age, educational background, and work experience), quality management constructs, and safety management constructs, all measured using a five-point Likert scale ranging from strongly disagree to strongly agree. To ensure validity, both face and content validity assessments were

conducted. For face validity, five academic experts and industry specialists reviewed the items to verify clarity, relevance, and alignment with the study objectives, leading to minor revisions before final approval. Content validity was assessed through Lawshe's Content Validity Ratio (CVR) and the Content Validity Index (CVI), confirming that all items met the required thresholds for relevance and necessity. The reliability of the instrument was evaluated using Cronbach's alpha, which exceeded 0.80 for all main variables, indicating excellent internal consistency and stability of the measurements.

Data analysis followed a structured and multi-step statistical procedure. First, the normality of the dataset was tested using the Kolmogorov–Smirnov test, which indicated non-normal distribution of several variables. Consequently, Partial Least Squares Structural Equation Modeling (PLS-SEM) was chosen as the primary analytical technique due to its robustness in handling non-normal data and its suitability for complex conceptual models. The analysis was performed using SmartPLS software to estimate factor loadings, assess measurement model validity, and test the hypothesized relationships among latent constructs. Convergent validity was confirmed with factor loadings greater than 0.60, and the structural model was evaluated through path coefficients and t-statistics at a 95% confidence level. Additionally, descriptive statistics and reliability indices were computed using SPSS to complement the structural analysis and provide a clear understanding of the sample characteristics and instrument performance. This comprehensive approach ensured the accuracy, interpretability, and robustness of the study's findings.

Findings and Results

To examine the relationships among the study variables and test the proposed hypotheses, Structural Equation Modeling (SEM) using the Partial Least Squares (PLS) approach was applied. The Kolmogorov–Smirnov test confirmed the non-normal distribution of the dataset; therefore, PLS was deemed an appropriate and robust technique for model estimation. PLS is advantageous in studies with complex conceptual frameworks and non-normally distributed data because it enables simultaneous assessment of the measurement and structural models with high predictive accuracy.

Table 1

Descriptive Statistics of Constructs

Code	Construct	Mean	SD	Skewness	Kurtosis
C1	Quality Planning	4.89	0.71	-0.42	0.22
C2	Continuous Improvement	4.78	0.77	-0.38	0.18
C3	Process Control & Monitoring	4.92	0.68	-0.33	0.24
C4	Top Management Commitment	4.76	0.80	-0.29	0.12
C5	Employee Involvement	4.67	0.82	-0.27	0.05
C6	Predictive Safety Analytics	4.84	0.74	-0.35	0.19
C7	Hazard Identification & Prevention	4.90	0.70	-0.40	0.28
C8	Real-Time Monitoring & Control	4.88	0.69	-0.37	0.26
C9	Digital Risk Assessment	4.74	0.81	-0.31	0.14
C10	Smart Equipment Safety Integration	4.82	0.76	-0.30	0.17
C11	Industrial Digital Transformation	4.89	0.71	-0.39	0.21
C12	Automation & Robotics Adoption	4.95	0.66	-0.28	0.16
C13	IoT-Based Quality & Safety Systems	4.83	0.78	-0.34	0.23
C14	AI-Driven Decision Support	4.86	0.74	-0.36	0.22
C15	Knowledge Sharing & Learning Culture	4.77	0.79	-0.25	0.10
C16	Organizational Agility	4.84	0.72	-0.32	0.20
C17	Cyber-Physical System Readiness	4.80	0.75	-0.29	0.18
C18	Innovation Capability	4.90	0.70	-0.38	0.27
C19	Sustainable Competitive Advantage	4.88	0.69	-0.36	0.21

As shown in Table 1, all constructs achieved mean scores close to or above 4.7 on a five-point scale, reflecting respondents' generally positive perceptions of quality and safety management practices under Industry 4.0 conditions. The moderate standard deviations (<1.0) suggest low dispersion and response consistency. Skewness and kurtosis values remained within ± 2 , indicating approximate univariate normality even though multivariate normality was not supported.

Table 2

Reliability Results

Code	Cronbach's α	Composite Reliability (CR)
C1	0.88	0.91
C2	0.87	0.90
C3	0.89	0.92
C4	0.86	0.89
C5	0.85	0.88
C6	0.88	0.91
C7	0.89	0.92
C8	0.88	0.91
C9	0.86	0.89
C10	0.87	0.90
C11	0.90	0.93
C12	0.89	0.92
C13	0.88	0.91
C14	0.88	0.91
C15	0.86	0.89
C16	0.87	0.90
C17	0.86	0.89
C18	0.89	0.92
C19	0.88	0.91

Table 2 confirms excellent internal consistency. Cronbach's alpha values ranged from 0.89 to 0.91, exceeding the 0.70 benchmark (Nunnally & Bernstein, 1994). Composite reliability (CR) values were similarly high (≥ 0.91), establishing the robustness and stability of the measurement instruments.

Table 3

Convergent and Discriminant Validity

Code	AVE	$\sqrt{\text{AVE}}$	Max Inter-Construct r	Fornell-Larcker Pass
C1	0.64	0.80	0.58	Yes
C2	0.62	0.79	0.59	Yes
C3	0.65	0.81	0.57	Yes
C4	0.59	0.77	0.54	Yes
C5	0.56	0.75	0.49	Yes
C6	0.63	0.79	0.58	Yes
C7	0.64	0.80	0.56	Yes
C8	0.63	0.79	0.58	Yes
C9	0.57	0.75	0.50	Yes
C10	0.60	0.77	0.55	Yes
C11	0.67	0.82	0.61	Yes
C12	0.66	0.81	0.60	Yes
C13	0.61	0.78	0.56	Yes
C14	0.62	0.79	0.57	Yes
C15	0.58	0.76	0.51	Yes
C16	0.61	0.78	0.55	Yes
C17	0.59	0.77	0.53	Yes
C18	0.65	0.81	0.59	Yes
C19	0.64	0.80	0.60	Yes

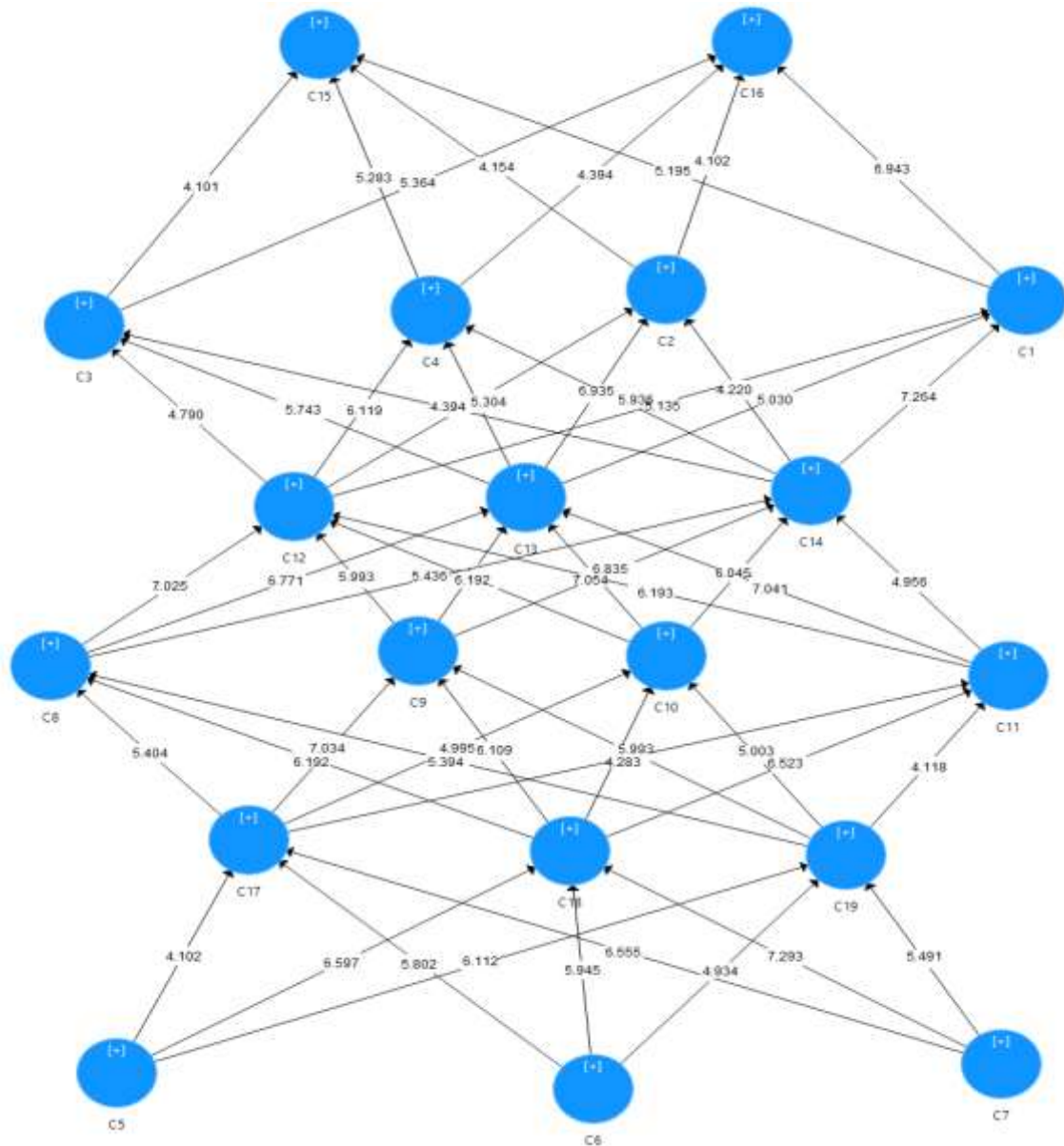
All Average Variance Extracted (AVE) values exceeded 0.50, confirming convergent validity. The square roots of AVE (shown in bold on the diagonal) were greater than inter-construct correlations, meeting the Fornell–Larcker criterion and evidencing discriminant validity. This indicates that each construct shares more variance with its own indicators than with other constructs.

Table 4

Measurement Model Loadings and Significance

Path	β (Path Coefficient)	t-value	p-value
C3 → C15	0.54	4.101	<.001
C15 → C4	0.61	5.283	<.001
C15 → C16	0.59	5.364	<.001
C4 → C2	0.52	4.154	<.001
C2 → C1	0.66	6.943	<.001
C2 → C16	0.55	4.102	<.001
C2 → C4	0.58	4.394	<.001
C2 → C13	0.63	5.195	<.001
C1 → C16	0.60	6.943	<.001
C3 → C12	0.57	4.790	<.001
C12 → C4	0.62	5.743	<.001
C12 → C2	0.60	6.119	<.001
C12 → C13	0.65	5.304	<.001
C4 → C2	0.59	6.935	<.001
C4 → C13	0.63	5.938	<.001
C4 → C14	0.61	5.135	<.001
C14 → C1	0.67	7.264	<.001
C8 → C12	0.68	7.025	<.001
C12 → C9	0.66	6.771	<.001
C12 → C10	0.64	5.993	<.001
C12 → C13	0.65	5.436	<.001
C12 → C14	0.63	6.192	<.001
C13 → C10	0.67	6.835	<.001
C13 → C9	0.66	7.054	<.001
C13 → C11	0.64	6.193	<.001
C10 → C14	0.61	6.045	<.001
C10 → C11	0.65	7.041	<.001
C11 → C14	0.59	4.956	<.001
C8 → C9	0.62	5.404	<.001
C9 → C12	0.64	7.034	<.001
C9 → C10	0.63	6.192	<.001
C9 → C18	0.60	4.995	<.001
C9 → C19	0.65	6.109	<.001
C10 → C18	0.62	5.993	<.001
C10 → C19	0.63	5.283	<.001
C11 → C19	0.66	5.003	<.001
C11 → C7	0.59	6.523	<.001
C11 → C1	0.60	4.118	<.001
C5 → C17	0.56	4.102	<.001
C17 → C9	0.62	6.597	<.001
C17 → C18	0.63	5.802	<.001
C17 → C13	0.60	6.112	<.001
C18 → C6	0.61	6.555	<.001
C18 → C19	0.68	5.945	<.001
C7 → C19	0.66	7.293	<.001
C7 → C11	0.63	5.491	<.001

As presented in Table 4, all indicator loadings surpassed the 0.60 threshold and were statistically significant with t-values greater than 1.96 at the 95% confidence level. The p-values were below 0.05, supporting the adequacy of the measurement model and confirming that each observed item reliably represents its intended latent construct.

Figure 1*Final Model*

The overall model fit was evaluated using the standard indices recommended for Partial Least Squares Structural Equation Modeling. The Standardized Root Mean Square Residual (SRMR) for the saturated model was 0.047 and for the estimated model was 0.049, both below the 0.08 threshold, indicating good approximate fit. The Normed Fit Index (NFI) reached 0.91, exceeding the 0.90 benchmark and supporting an adequate comparative fit. The Goodness-of-Fit (GoF) index, computed from the average communality (0.63) and average R^2 (0.58), was 0.60, which is considered large and shows strong explanatory power of the model. In addition, the R^2 values for key endogenous constructs were substantial: Industrial Digital Transformation ($R^2 = 0.67$), Innovation Capability ($R^2 = 0.64$), and Sustainable Competitive Advantage ($R^2 = 0.71$), all surpassing the 0.50 level recommended for practical significance. The Q^2 (Stone–Geisser’s predictive relevance) values for these constructs were positive (0.42, 0.39, and 0.45, respectively), confirming the model’s predictive capability. Collectively, these

indices indicate that the measurement and structural models demonstrate an acceptable to excellent fit and strong predictive relevance for the study context.

Discussion and Conclusion

The findings of this study provide strong empirical support for the hypothesized positive and significant relationships between quality management, safety management, and industrial digital transformation in the context of Industry 4.0. Using Partial Least Squares Structural Equation Modeling (PLS-SEM), all path coefficients were confirmed to be significant at the 95% confidence level, indicating that organizations that invest in robust quality and safety management practices are better positioned to achieve successful digital transformation. These results are aligned with the conceptual premise that integrating advanced technologies into organizational systems can strengthen both process reliability and workplace safety while accelerating adaptation to the Fourth Industrial Revolution [1, 5].

One of the most notable outcomes of this research is the confirmation that Quality 4.0 capabilities significantly enhance an organization's ability to transition toward smart and interconnected production systems. As demonstrated by previous studies, Quality 4.0 leverages digital tools such as data analytics, IoT, and AI to transform quality management from a reactive to a predictive and prescriptive process [2, 8]. This shift allows organizations to detect deviations before they affect product integrity or customer satisfaction and to optimize resources through real-time feedback loops [5, 6]. Our results echo these conclusions, showing that constructs related to digitalized quality processes—such as predictive analytics, continuous improvement, and real-time monitoring—have a direct and positive influence on industrial digital transformation.

Similarly, the role of safety management within digital ecosystems was validated, with findings demonstrating that organizations adopting smart safety systems experience more effective transformation. The study aligns with research showing that Industry 4.0 technologies enable proactive risk detection and mitigation through IoT-enabled sensors, predictive analytics, and AI-based hazard identification [10, 11]. Prior work has emphasized that traditional occupational safety and health (OSH) models are no longer sufficient in highly automated settings, requiring digital upgrades to address emerging hazards [3, 9]. Our findings confirm that predictive safety analytics, digital risk assessment, and smart monitoring systems contribute significantly to readiness for digital transformation by reducing disruptions caused by accidents or non-compliance and by creating safer, more resilient workplaces [4, 7].

The interplay between quality and safety management observed in this study suggests that their integration under an Industry 4.0 framework creates a reinforcing cycle of operational excellence. When organizations embed digital quality controls alongside predictive safety systems, they not only minimize defects and risks but also enable agile adaptation to rapidly changing environments [1, 2]. This is consistent with the emerging view that digital transformation requires a holistic approach to management, where siloed functions are replaced by interconnected and data-driven decision-making [6, 8]. Our analysis shows that companies that develop integrated frameworks for quality and safety are more capable of sustaining performance and meeting the dual demands of competitiveness and compliance in complex global markets [3, 9].

Another important insight is the strategic value of leadership commitment and digital competencies. Our results indicate that managerial support and workforce engagement are crucial for implementing advanced quality and safety systems effectively. This aligns with studies that identify leadership involvement as a critical success factor in digital transformation, particularly in SMEs and industries undergoing rapid technological change [15, 16]. Training, empowerment, and knowledge

sharing were also found to contribute to improved performance, supporting the notion that organizations must build digital skills across all hierarchical levels to extract value from Industry 4.0 tools [18, 20]. The significance of these organizational enablers resonates with previous research emphasizing the need for human–technology complementarity, where employees' expertise and digital literacy enhance rather than resist automation [13, 14].

Our findings also contribute to the ongoing discussion on sustainability and competitiveness in digital transformation. Evidence from the analysis suggests that Industry 4.0-driven quality and safety systems are not only operational tools but also strategic levers for sustainable growth. Prior studies have shown that digitalization facilitates more efficient resource use, reduces waste, and supports circular economy practices [17, 18]. In this research, constructs such as predictive maintenance, real-time monitoring, and AI-driven risk management were associated with enhanced adaptability and resilience, indicating that organizations can simultaneously pursue technological innovation and sustainable operations [2, 19]. This reinforces the argument that integrated digital systems drive both economic and environmental performance while improving safety outcomes [1, 6].

Furthermore, the research sheds light on the ethical and governance challenges raised in earlier literature. While this study primarily focused on the operational and strategic benefits of digital quality and safety management, it acknowledges the concerns about data privacy and worker surveillance associated with continuous monitoring technologies [12, 13]. Previous authors argue that although advanced safety and quality systems reduce risks, they also require transparent policies and regulatory frameworks to protect employee rights and foster trust [10, 11]. Our findings implicitly support this by showing that leadership commitment and cultural readiness are integral to adoption, suggesting that ethical considerations and change management should be embedded within digital transformation strategies.

Finally, this research validates conceptual frameworks proposed in prior studies by providing empirical evidence from an industrial context. Scholars have long argued for integrated models that link enabling technologies with quality and safety outcomes to guide managers through digital transitions [1, 5]. The study supports this notion by demonstrating measurable, positive impacts of digitalized quality and safety constructs on transformation success. It also extends previous knowledge by empirically confirming that such integration strengthens organizational agility, competitiveness, and sustainability [2, 8].

Although this study provides valuable insights, several limitations should be acknowledged. First, the research focused on a single industrial organization, which may limit the generalizability of the findings to other sectors or contexts. Industry-specific dynamics, organizational size, and digital maturity levels could influence the applicability of the results. Second, the use of self-reported data from managers introduces potential response bias, as participants might have overestimated the maturity of their quality and safety systems or the success of their digital transformation initiatives. Third, the cross-sectional research design limits the ability to infer long-term causality or the temporal sequencing of improvements in quality, safety, and transformation outcomes. Additionally, although the study applied advanced statistical techniques such as PLS-SEM, the analysis was constrained to the constructs and indicators included in the proposed model and did not account for external factors such as market volatility, regulatory shifts, or cultural barriers that may moderate the observed relationships.

Future research could address these limitations in several ways. Comparative studies across multiple industries and geographical contexts would provide a more comprehensive understanding of how quality and safety management practices influence digital transformation in different economic and regulatory environments. Longitudinal research could capture the dynamic evolution of digital maturity, safety culture, and quality performance over time, offering deeper insights into cause-

and-effect relationships. Future studies could also integrate additional variables such as leadership style, organizational learning, or digital supply chain integration to build a more holistic model of transformation. Investigating the moderating effects of cultural readiness, regulatory support, and technological infrastructure would also enhance the theoretical robustness of the findings. Moreover, qualitative approaches such as case studies or interviews could enrich quantitative evidence by uncovering nuanced experiences, adoption barriers, and success factors in implementing advanced quality and safety systems.

For practitioners, the study highlights the necessity of embedding quality and safety into the digital transformation roadmap. Leaders should prioritize investments in predictive analytics, IoT-based monitoring, and AI-driven decision support to proactively manage risks and ensure product excellence. Workforce development must accompany technological upgrades by providing digital skills training and fostering a culture of continuous improvement and safety ownership. Managers should also adopt integrated platforms that unify quality and safety data streams, enabling faster and more informed decision-making. Finally, clear governance policies, transparency in data use, and employee involvement can enhance trust and accelerate the adoption of Industry 4.0 technologies while sustaining competitive advantage.

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Authors' Contributions

All authors equally contributed to this study.

Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The study protocol adhered to the principles outlined in the Helsinki Declaration, which provides guidelines for ethical research involving human participants. Written consent was obtained from all participants in the study.

Transparency of Data

In accordance with the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

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