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FROM SUBJECTIVITY TO COMPUTATIONAL INTELLIGENCE: A BIBLIOMETRIC REVIEW AND QUALITATIVE ANALYSIS OF PFMEA APPROACHES IN THE CONTEXT OF INDUSTRY 4.0

DA SUBJETIVIDADE À INTELIGÊNCIA COMPUTACIONAL: UMA REVISÃO BIBLIOMÉTRICA E ANÁLISE QUALITATIVA DE ABORDAGENS PFMEA NO CONTEXTO DA INDÚSTRIA 4.0

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ABSTRACT

The present study analyzes the evolution and applications of Process Failure Mode and Effects Analysis (PFMEA) within the context of Production Engineering and Industry 4.0 through a bibliometric review and qualitative analysis of 15 articles published between 2010 and 2025. The

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objective is to understand how PFMEA has been applied and enhanced, highlighting methodological advances and its contribution to structuring, standardizing, and improving production processes. The results indicate a significant increase in publications after 2016, particularly in the manufacturing and automotive sectors, driven by the need for greater reliability and technological integration. Notable methodological advances include integrating PFMEA with multicriteria decision-making tools, fuzzy logic, Monte Carlo simulation, computational intelligence, and data mining techniques to reduce the subjectivity of the traditional method and improve risk prioritization. Furthermore, PFMEA applications have expanded to areas such as healthcare, material recycling, and academic laboratories, although its use remains predominantly industrial. The analyzed studies report benefits, including reduced failures, improved operational robustness, enhanced decision-making support, and increased process safety. It is concluded that PFMEA remains an essential tool for Production Engineering in the digital era, contributing to the development of more efficient, reliable, and Industry 4.0-oriented processes. This study consolidates current trends and research opportunities, reinforcing the importance of integrating PFMEA with emerging technologies.

Keywords: PFMEA; Production Engineering; Industry 4.0; Risk Management; Failure Analysis; Production Processes; Operational Reliability.

RESUMO

O presente artigo analisa a evolução e as aplicações do Process Failure Mode and Effects Analysis (PFMEA) no contexto da Engenharia de Produção e da Indústria 4.0, por meio de uma revisão bibliométrica e análise qualitativa de 15 artigos publicados entre 2010 e 2025. O objetivo é compreender como o PFMEA tem sido aplicado e aprimorado, destacando avanços metodológicos e sua contribuição para estruturar, padronizar e aperfeiçoar processos produtivos. Os resultados mostram um crescimento significativo das publicações após 2016, especialmente em setores como manufatura e automotivo, impulsionado pela necessidade de maior confiabilidade e integração tecnológica. Destacam-se avanços metodológicos que combinam PFMEA com ferramentas multicritério, lógica fuzzy, simulação de Monte Carlo, inteligência computacional e técnicas de mineração de dados, com o objetivo de reduzir subjetividades do método tradicional e melhorar a priorização de riscos. Além disso, observa-se expansão do uso do PFMEA para áreas como saúde, reciclagem de materiais e laboratórios acadêmicos, embora sua aplicação ainda seja majoritariamente industrial. Os estudos analisados apontam benefícios como redução de falhas, maior robustez operacional, suporte à tomada de decisões e maior segurança de processos. Conclui-se que o PFMEA permanece essencial para a Engenharia de Produção na era digital e contribui para o desenvolvimento de processos mais eficientes, confiáveis e alinhados às demandas da Indústria 4.0. O estudo consolida tendências e oportunidades de pesquisa, reforçando a importância da integração do PFMEA com tecnologias emergentes.

Palavras-chave: PFMEA, Engenharia de Produção, Indústria 4.0, Gestão de riscos, Análise de falhas, Processos produtivos, Confiabilidade operacional.

1. INTRODUCTION

The current competitive environment requires organizations to improve their processes continuously. According to Deming (1986) and Juran (1992), quality management is founded on the principles of continuous improvement and failure prevention, which are also reflected in international standards such as ISO 9001:2015 (ISO, 2015).

However, quality is no longer regarded as a competitive differentiator; rather, it has become a fundamental market requirement. Customers now expect reliable products and services as a minimum standard, while competitive differentiation is achieved through innovation, customer experience, and operational efficiency (HOWTOLAB, 2023; IMIRANTE, 2024; MEDIUM, 2023).

Several strategies have been adopted to meet these market requirements, including product development (González Aleu, Garza-Reyes, 2020), continuous improvement projects (Mesquita, Alliprandini, 2014), durability and reliability testing (SAE International, 2013), stress testing (Jardine; Tsai, Fu, 2015), process capability studies (Geramian *et al.*, 2021), Measurement System Analysis (MSA) (Pawlak, Radzikowska, 2018), and Failure Mode and Effects Analysis (FMEA) (SAE International, 2009), among other approaches.

When specifically considering FMEA, two primary applications can be identified: Design Failure Mode and Effects Analysis (DFMEA) and Process Failure Mode and Effects Analysis (PFMEA). DFMEA focuses on identifying potential product failures during the design phase, whereas PFMEA addresses potential failures in manufacturing and assembly processes. These approaches are widely recognized in technical standards and guidelines, including the *AIAG & VDA FMEA Handbook* (AIAG, VDA, 2019) and the automotive quality management requirements established by IATF 16949, while remaining consistent with the risk-based thinking principles embedded in ISO 9001:2015.

Within this context, Process Failure Mode and Effects Analysis (PFMEA) plays a strategic role by identifying potential process failures during the planning and development stages and proposing preventive actions to ensure the minimum quality standards required by the market. Furthermore, Industry 4.0 technologies—including digitalization, advanced automation, and real-time data analytics—have significantly enhanced PFMEA applications. The use of smart sensors, continuous process monitoring, and integrated information systems enables earlier failure detection, improves process reliability, and reduces rework.

PFMEA has been applied across a wide range of industrial and service sectors, including automotive, aerospace, and healthcare, and has become the subject of numerous academic studies. Research by Bujna et al. (2023) and Bozola et al. (2023) highlights its application in the automotive sector, while Wu et al. (2022) investigate its use in complex aerospace manufacturing processes. In healthcare, Górski et al. (2022) applied PFMEA to the production of customized prostheses, whereas Kornek and Bert (2024) employed the methodology in radiotherapy, demonstrating its relevance in medical contexts. Silva et al. (2020) integrated PFMEA into risk management practices in academic laboratories, extending its application to research and service environments. These studies encompass a wide variety of methodological approaches, ranging from case studies to innovative methodological developments, revealing a fertile field for comprehensive analyses that synthesize and discuss recent contributions.

Given this scenario, the research problem addressed in this study is to understand how PFMEA applications and methodological advances have been employed to enhance failure identification and risk prioritization in processes, and to assess the implications of these developments for reliability, quality, and decision-making across sectors. Accordingly, the following research question is proposed: How have recent studies applied and improved PFMEA to enhance failure identification and prioritization in processes, and what are the implications of these advances for reliability, quality, and decision-making across different industrial and organizational contexts?

To answer this question, the present study aims to critically analyze the applications and methodological advances of Process Failure Mode and Effects Analysis (PFMEA) and its variations across industrial and organizational contexts, and to identify how recent approaches improve the identification, prioritization, and mitigation of risks in manufacturing and service processes.

From an academic perspective, this research is relevant because it consolidates a field that still lacks comprehensive review studies, providing an integrated overview of how PFMEA has evolved to meet the challenges of Industry 4.0. By systematizing methods and emerging trends, this study advances scientific knowledge in Production Engineering and provides a theoretical foundation for future research on reliability, quality, and risk management (Braglia et al., 2021; Das, Panchal, & Tyagi, 2022; Komatina et al., 2025).

From a managerial perspective, the study provides practitioners and decision-makers with practical evidence to support decision-making, failure prioritization, and the continuous improvement of organizational processes. Recent studies indicate that integrating risk management, maintenance, and quality management is essential for improving organizational reliability and competitiveness (Bozola et al., 2023; Zeng, Shao, & Hao, 2021). Therefore, understanding how PFMEA has been adapted to Industry 4.0 requirements enables organizations to strengthen their management systems, improve operational performance indicators, and enhance failure prevention practices in line with ongoing digital transformation.

Therefore, this study is justified by both its theoretical relevance—through the consolidation of methodological advances and the identification of research gaps—and its practical importance, as it guides the more effective application of PFMEA in complex production environments, thereby contributing to the development of more reliable, innovative, and Industry 4.0-oriented processes.

2. METHOD

This section presents the methodological procedures used to conduct the bibliometric review of the selected PFMEA studies, including the article selection process, data collection and organization, and the quantitative and qualitative analysis techniques employed.

2.1 Research Approach

This study is characterized as exploratory and descriptive, adopting a quantitative and systematic approach, as defined by Gil (2008), since it aims to map, analyze, and describe the scientific literature on PFMEA published between 2010 and 2025. Bibliometric analysis was employed as the primary research method to identify publication patterns, scientific collaborations, and thematic trends within the selected studies.

2.2 Selection Criteria

The articles analyzed were retrieved from the Scopus database between May and July 2025 using the search term "PFMEA." The selection process considered studies directly related to the research topic, published between 2010 and 2025. Selection criteria included citation count, academic impact, and diversity of industrial sectors and application areas. Only peer-reviewed journal articles written in English were included.

Following the initial screening, studies without a complete PDF version were excluded. Subsequently, the titles, abstracts, and full texts were reviewed to confirm their thematic relevance. This process resulted in a final sample of the 15 most highly cited articles.

2.3 Data Collection and Organization

For each selected article, information regarding the title, publication year, keywords, research objectives, and research methods was extracted. These data were organized in a Microsoft Excel spreadsheet to support subsequent quantitative and qualitative analyses. This organization enabled the classification of publications according to publication period and research theme, the quantification of studies by year, and the development of graphical representations illustrating the main findings.

The tables and figures are presented in the Results section of this study. Table 1 summarizes the authors, research objectives, and methodologies.

2.4 Bibliometric Analysis Procedures

The bibliometric analysis was conducted using a quantitative, descriptive approach to examine the evolution of PFMEA-related publications and to characterize the scientific output in this field. The analysis focused on the annual publication volume, document types, and predominant application areas, according to the classification available in the Scopus database.

3. RESULTS

This section presents the main findings obtained from the analysis of the selected studies. First, the research objectives and methodologies adopted in each study are described. Next, the principal findings are highlighted, emphasizing both methodological and practical advances. Finally, the theoretical and practical contributions are synthesized to provide a comprehensive understanding of how each study advances scientific knowledge and supports process management across diverse industrial and organizational contexts.

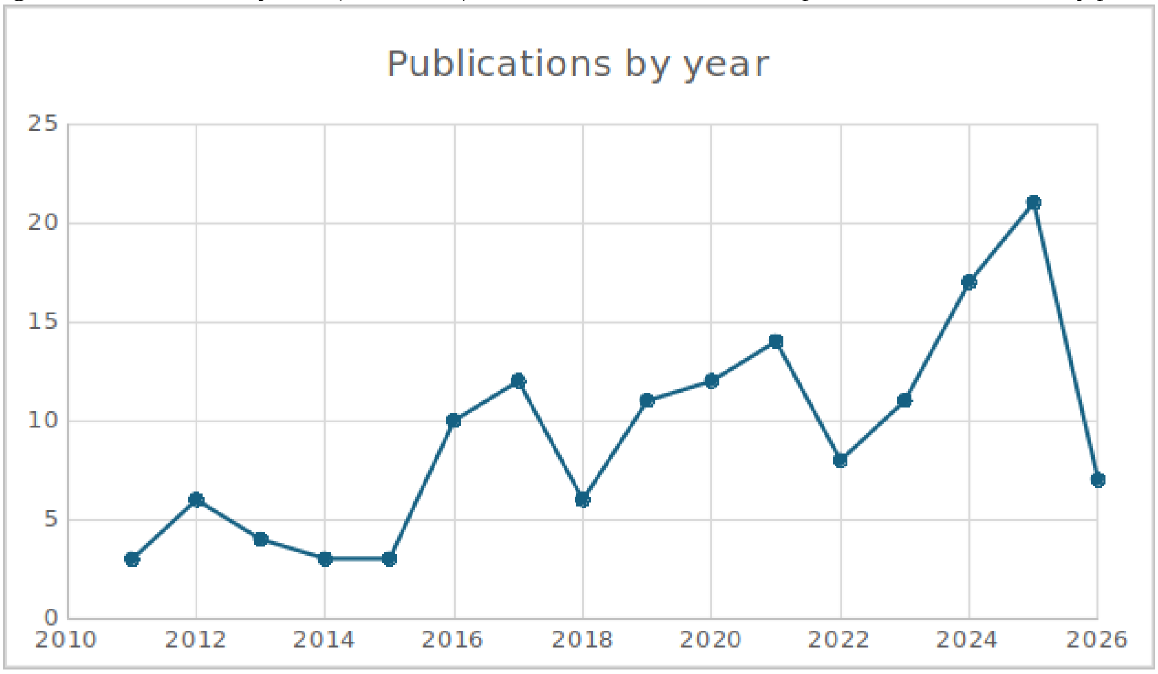
To facilitate the interpretation of the findings, the data summarized in Tables 1 and 2 were complemented by graphs and a word cloud, providing a visual synthesis of the scientific literature on PFMEA. Each of these results is presented and discussed in the following sections.

3.1 Publications by Year

The temporal evolution of PFMEA-related publications from 2010 to 2025 is shown in Figure 1. The data reveal a substantial increase in the number of publications beginning in

2016, with more pronounced growth in recent years. This trend indicates a growing academic and industrial interest in the application and continuous development of PFMEA over the past decade.

Figure 1 – Publications by Year (2010–2025). Evolution of PFMEA-related publications over the study period.



3.2 Application Areas by Publication

Figure 2 presents the main application areas of PFMEA. Engineering accounts for the largest share of publications, followed by Business, Management and Accounting, and Mathematics. Other fields, such as Social Sciences, Medicine, and Health Professions, appear less frequently, highlighting both the multidisciplinary nature of PFMEA and its potential for broader application across diverse domains.

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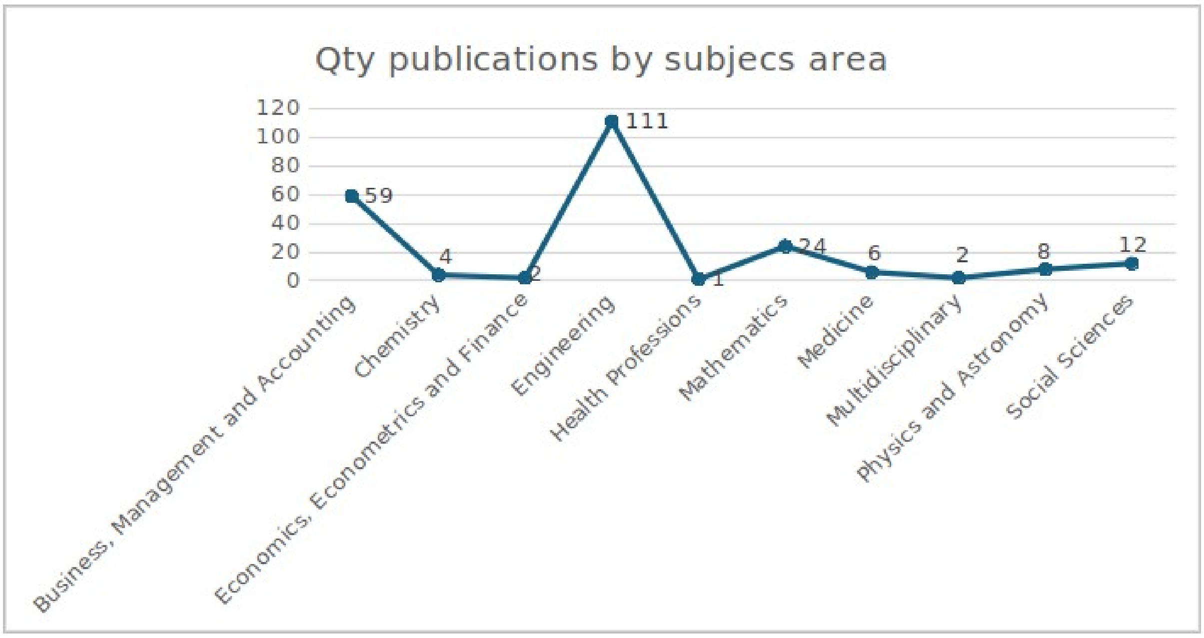
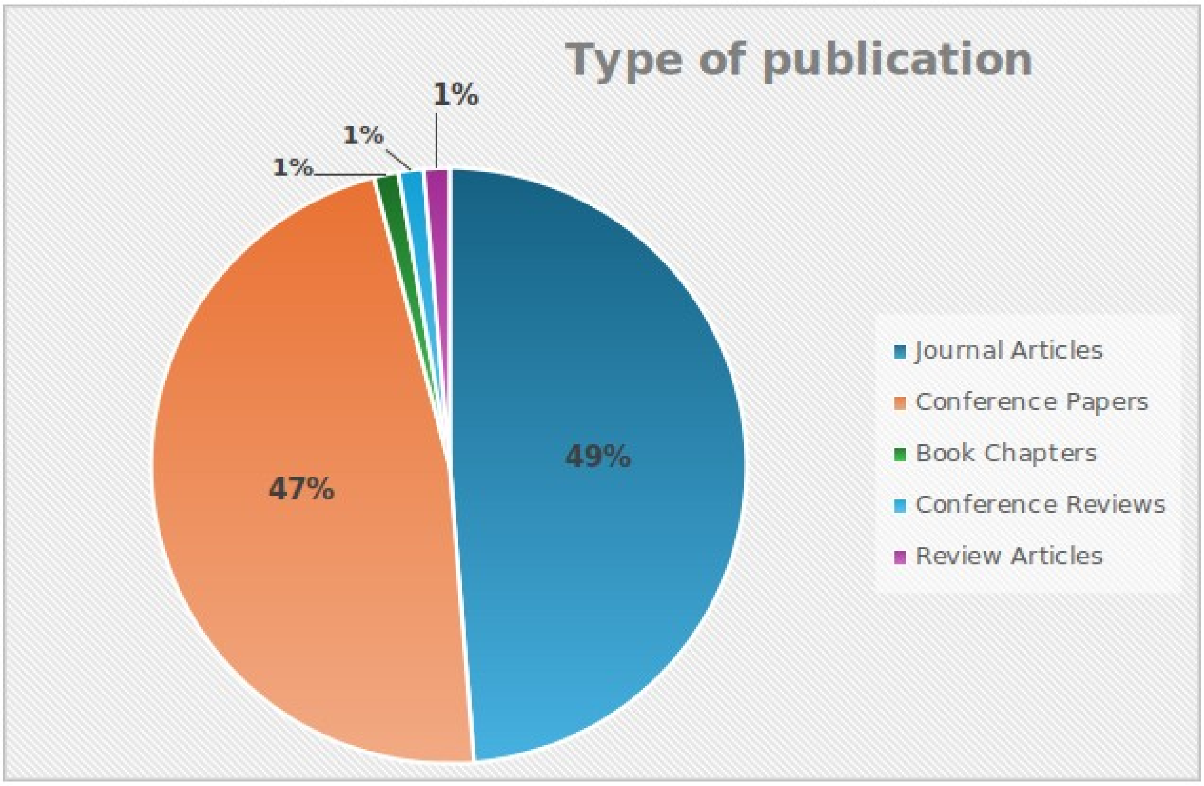
Figure 2 – Publications by Application Area. Distribution of PFMEA-related publications by application area.



3.3 Document Types

Figure 3 summarizes the types of documents published on PFMEA between 2010 and 2025. Journal articles and conference papers account for the majority of the scientific output, whereas book chapters and review articles represent a relatively small proportion of the publications.

Figure 3 – Document Types. Distribution of journal articles, conference papers, book chapters, and review articles on PFMEA published between 2010 and 2025.



3.4 Research Objectives and Methods Employed

The first stage of the analysis consisted of examining the authors of the selected studies, the objectives of each article, and the research methods employed. The results of this analysis are summarized in Table 1.

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Table 1 – Authors, Research Objectives, and Research Methods of the Reviewed Studies

Authors	Research Objective	Research Method
Yousefi, Rezaee & Moradi (2020)	To propose an intelligent method for identifying and prioritizing risks in manufacturing logistics processes by overcoming the limitations of the traditional Risk Priority Number (RPN) by incorporating causal relationships among logistics subprocesses and the severity, occurrence, and detection factors.	The study was conducted through a case study in the automotive industry, integrating Process Failure Mode and Effects Analysis (PFMEA) with the Sequential Multi-Stage Fuzzy Cognitive Map (SMFCM) model. The research adopted an applied and exploratory approach based on a single case study, combining computational modeling, expert judgment, and machine-learning algorithms (Extended Delta Rule), characterizing an empirical investigation supported by both quantitative and qualitative techniques.
Zeng, Shao & Hao (2021)	To develop preventive maintenance strategies for beer filling equipment in a Chinese brewery based on operational reliability, aiming to reduce maintenance costs, minimize unplanned failures, and increase production availability through the application of Reliability-Centered Maintenance (RCM).	An applied case study was conducted in a beer filling production line. Failure records, downtime, and maintenance data were collected over 12 months and analyzed using reliability indicators (MTBF, MTTR, and availability). The methodology integrated PFMEA, Fault Tree Analysis (FTA), and Reliability-Centered Maintenance (RCM), characterizing an empirical-analytical approach for maintenance decision-making.
Kapustka et al. (2020)	To analyze the technological and managerial challenges associated with recovering neodymium permanent magnets from waste electrical and electronic equipment (WEEE), and to propose improvements to the recycling process based on Process Failure Mode and Effects Analysis (PFMEA) to enable industrial reuse of these strategic materials.	The research was conducted in a laboratory setting using a prototype production line to recycle NdFeB magnets recovered from electronic waste. The study employed an applied, experimental approach with a strong technological orientation, using PFMEA to identify potential process failures. It combined principles of process management and materials engineering while incorporating Industry 4.0 concepts and quality standards (ISO 9000 and IEC 60812), characterizing an empirical investigation focused on sustainable process improvement.
Górski et al. (2022)	To apply Process Failure Mode and Effects Analysis (PFMEA) to the manufacturing process of customized upper-limb prostheses produced via 3D scanning and 3D printing to identify critical risks and propose improvements that reduce the number of iterations required to obtain well-fitting, functional prostheses.	The study employed an applied, exploratory case study involving an adult patient who used the AutoMedPrint system. The production process was divided into three main subprocesses (data acquisition, data processing, and product preparation), each evaluated using PFMEA. The methodology included qualitative analysis based on severity, occurrence, and detection (SOD) criteria, supported by technical and clinical experts, as well as complementary quality tools such as the Ishikawa diagram and process mapping, following the AIAG & VDA FMEA framework adapted for healthcare applications.
Das, Panchal & Tyagi (2022)	To develop a decision-support system based on PFMEA integrated with the Doubly Fuzzy TOPSIS (DTOPSIS) method for risk analysis in the milk pasteurization process, overcoming	The study employed an applied exploratory case study in a milk-processing plant located in Jalandhar, India. The methodology combined PFMEA for failure identification, fuzzy expert evaluations, and the DTOPSIS algorithm for

Authors	Research Objective	Research Method
	the limitations of conventional PFMEA and rule-based fuzzy models while improving failure prioritization and preventive maintenance.	ranking critical failure causes. Consistency tests comparing the proposed model with fuzzy TOPSIS and VIKOR were also performed to improve analytical robustness.
Wu et al. (2022)	To propose an innovative method for the automatic identification of potential process failure modes (PPFM) in high-mix, low-volume manufacturing environments by integrating Process Constituent Elements (PCE), case-based reasoning, and Natural Language Processing (NLP), thereby improving the efficiency, completeness, and accuracy of failure identification.	The research adopted an applied and exploratory methodology with a strong emphasis on computational intelligence and process modeling. The procedure involved decomposing the process into six PCE dimensions, standardizing process instructions through data mining, applying extension theory for case representation, and using NLP together with case-based reasoning to identify process failure modes. The proposed model was validated through a practical case study involving aircraft component assembly.
Sun, Yeh & Pai (2022)	To apply Monte Carlo simulation to evaluate the confidence level associated with severity, occurrence, and detection (S, O, and D) assessments within the Action Priority (AP) framework of the AIAG & VDA FMEA Handbook. The study aims to quantify uncertainties inherent in qualitative FMEA assessments and propose a probabilistic decision-support model for industrial risk management.	The research adopted a quantitative applied approach based on statistical modeling and computational simulation. Monte Carlo simulation with non-uniform discrete distributions was employed to estimate possible combinations of S, O, and D values. Simulations comprising 1,000 iterations per event were performed using Crystal Ball software with a 95% confidence interval. Two semiconductor manufacturing case studies were used to compare the proposed probabilistic approach with the traditional Risk Priority Number (RPN) method.
Braglia et al. (2021)	To propose a revised Process Failure Mode and Effects Analysis (PFMEA) approach to support the reliable design of complex product assembly activities by integrating PFMEA into the early design phase. The proposed framework seeks to overcome the limitations of conventional PFMEA by preventing assembly-related defects and improving reliability through additional standardization elements and operator support.	The study adopted an applied, exploratory approach based on a case study of a railway freight wagon manufacturing company. The methodology combined PFMEA with qualitative assessment tools, process decomposition worksheets, and standardized Design-Job Element Sheets (D-JES). A multidisciplinary team of experts in design, manufacturing, quality, and logistics collaborated for six months to validate potential failure modes and causes, and to recommend corrective actions.
Bujna et al. (2023)	To develop a hybrid model that integrates Process Failure Mode and Effects Analysis (PFMEA) with the DEMATEL and Extended Risk Priority Number (ERPN) methodologies to overcome the limitations of conventional PFMEA. The proposed model aims to support manufacturers in post-communist economies by improving failure prioritization and incorporating the analysis of internal and external failure costs.	The study adopted an applied exploratory approach based on a case study of a transfer-pressing process used in the production of automotive brake components. The methodology initially applied PFMEA to identify 54 potential failure modes, then used DEMATEL to determine cause-and-effect relationships, and finally applied ERPN to extend traditional risk prioritization by incorporating internal and external failure costs. The evaluation team consisted of nine members, including project managers, quality and production specialists, and academic researchers, ensuring methodological robustness through multidisciplinary

Authors	Research Objective	Research Method
		expertise.
Li, Liu & Lin (2023)	To develop a quality prediction model for discrete manufacturing processes by integrating Process Failure Mode and Effects Analysis (PFMEA), the Analytic Hierarchy Process (AHP), and Grey System Theory. The proposed model seeks to overcome limitations in noisy and anomalous production data by introducing offset operators and denoising techniques, thereby improving predictive accuracy.	The research adopted an applied quantitative approach based on mathematical modeling and data analysis. The methodology involved: (i) constructing an AHP-PFMEA hierarchical model to identify and prioritize critical processes and workstations; (ii) introducing compensation operators to eliminate data disturbances; (iii) applying spectral analysis and moving-average denoising techniques; and (iv) developing a Discrete Grey Prediction Model (DGM (1,1)). The model was validated using sensor data collected from a semiconductor manufacturing production line.
Komatina et al. (2025)	To enhance Process Failure Mode and Effects Analysis (PFMEA) by applying the Fuzzy Ranking based on the Distances and Range (FRADAR) method within the automotive industry. The proposed approach aims to overcome the limitations of conventional Risk Priority Number (RPN) and Action Priority (AP) methods by incorporating multiple decision criteria and fuzzy uncertainty modeling.	The study employed an applied quantitative methodology based on fuzzy multicriteria decision-making (MADM). A case study was conducted in a Tier-1 automotive seat supplier, where 27 failure modes were identified during the sewing process, of which 16 were classified as high or medium priority. The methodology included an initial PFMEA analysis, RPN calculation, and the definition of four evaluation criteria (RPN value, cost-effectiveness of mitigation actions, implementation time, and production impact), followed by an FRADAR analysis using triangular fuzzy numbers to prioritize corrective actions.
Kornek & Bert (2024)	To develop a PFMEA template for External Beam Radiation Therapy (EBRT) based on a systematic literature review and to propose an adaptation of the Action Priority (AP) concept for radiation oncology, referred to as Radiation Oncology Action Priority (RO AP). The study aims to provide a standardized framework for risk analysis in radiotherapy and introduce more transparent and adaptable failure-prioritization criteria.	The research adopted an applied exploratory methodology that combined a systematic literature review of 126 publications on radiotherapy risks, including 43 specifically related to EBRT, with probabilistic modeling using Monte Carlo simulation. The methodology followed the AIAG PFMEA guidelines and resulted in a standardized template comprising 9 process stages, 33 subprocesses, and 112 functions. A new RO AP metric was proposed by combining weighted severity, occurrence, and detection scores and was compared with both the traditional RPN and the AIAG Action Priority approach.
Bozola et al. (2023)	To propose practical guidelines to support automotive companies in transitioning from ISO/TS 16949 to IATF 16949, taking into account the additional requirements introduced in the 2016 revision. The study aims to assist managers in implementing new practices related to product safety, corporate responsibility, total productive maintenance, supplier management, and quality system reliability.	The research employed an applied qualitative approach using multiple case studies of four automotive companies operating in Brazil. The methodology included semi-structured interviews with managers from different organizational levels, on-site observations, and document analysis of reports, internal procedures, and audit records. Evidence triangulation and cross-case analysis were employed to identify common and divergent implementation practices between ISO/TS 16949:2009 and IATF 16949:2016.

Authors	Research Objective	Research Method
Silva et al. (2020)	To propose an integrated risk management framework for academic research laboratories by combining HAZOP, PFMEA, and both digital and physical Poka-Yoke techniques. The study focuses on naphthenic corrosion experiments conducted in an electrochemistry and corrosion laboratory to improve physical and environmental safety while enhancing the reliability of experimental results.	The study adopted an applied exploratory case study conducted at the Federal University of Paraná (UFPR). The methodology comprised five stages: defining experimental requirements, developing detailed operating procedures, applying HAZOP and PFMEA through expert evaluations, creating integrated digital coversheets (Digital Poka-Yoke), and monitoring experimental execution. Eight naphthenic corrosion experiments were performed under continuous monitoring of critical variables, including pressure, temperature, and toxic gases (H_2S and O_2). Both digital and physical Poka-Yoke techniques were implemented to prevent operational errors.
Kar & Rai (2025)	To propose a modified Fuzzy PFMEA model for process evaluation from a Six Sigma perspective, considering risk assessment within the context of Industry 4.0 and Quality 4.0. The proposed framework integrates risk factors, Six Sigma performance metrics, and fuzzy logic to support more accurate predictive quality analysis in complex manufacturing environments.	The research adopted an applied quantitative approach based on mathematical modeling and multicriteria decision analysis. The methodology consisted of three phases: (i) identifying and evaluating potential failures using Fuzzy PFMEA integrated with the Analytic Network Process (ANP) to account for interdependencies among risk factors; (ii) developing a quality assessment model based on risk impact by translating occurrence and severity into Six Sigma metrics (yield, DPMO, and sigma level); and (iii) applying a value-risk matrix to visualize and prioritize alternatives. The proposed model was validated through a case study of additive manufacturing using Fused Filament Fabrication (FFF) to produce adjustable wrenches across five manufacturing workshops.

The first study demonstrated that the SMFCM-PFMEA method is more effective than the conventional Risk Priority Number (RPN) approach for risk prioritization because it more effectively differentiates critical threats by accounting for causal interdependencies among logistics subprocesses. The results showed that risks such as production line shutdowns due to equipment failures, shortages of production equipment, and supplier delivery failures have the greatest impact on the overall logistics system. The proposed model successfully ranked the 37 identified risks across eight logistics subprocesses, yielding a more realistic prioritization than the traditional RPN approach, which produces broad, less discriminative risk categories. Furthermore, incorporating a learning algorithm reduced reliance on subjective expert judgment, resulting in more consistent and less biased analyses. The study also demonstrated the practical applicability of the proposed approach in complex industrial environments, particularly in the automotive sector, where logistics reliability directly affects competitiveness. Overall, the findings confirm that integrating computational intelligence techniques enhances the robustness of risk analyses while providing managers with more effective support for preventive and corrective decision-making (Yousefi, Rezaee, & Moradi, 2020).

The second study revealed that the beer filling machine was the primary source of production line failures, exhibiting the highest failure frequency and the greatest impact on downtime. PFMEA identified eight potential failure modes, including bottle misalignment, overflow, inconsistent filling levels, and capping defects, each presenting different levels of risk. Fault Tree Analysis (FTA) further identified root causes, including component wear, valve failures, improper adjustments, and unsuitable operating conditions. Based on these findings, the authors proposed specific preventive strategies, including inspection plans, periodic adjustments, scheduled replacement of critical components, and the establishment of safety stock. The study demonstrated that implementing these practices could significantly reduce maintenance costs, decrease the probability of hidden failures, and improve production line availability. Furthermore, the authors recommended developing decision-support software based on reliability databases to automate risk calculations and improve the accuracy of maintenance strategies (Zeng, Shao, & Hao, 2021).

The third study identified three critical deficiencies in the initial production process: non-uniform distribution of magnetic particles within the composite material, material inconsistency, and inadequate geometry of the final products, all of which had Risk Priority Number (RPN) values above 120. To address these issues, five additional process operations were introduced, including preliminary chemical controls, particle size selection, microscopic inspections, and additional magnetic testing. Following implementation of these improvements, substantial reductions in RPN values were observed, particularly for failures associated with particle distribution and product geometry. However, material inconsistency remained partially unresolved, indicating the need for further optimization of the composite design, particularly the magnetic powder-to-polymer ratio. The study concluded that in-process controls and rigorous selection of recycled materials are essential for ensuring process stability and efficiency. Moreover, the findings confirmed that PFMEA is an effective tool for identifying critical risks during the early design phase, enabling preventive actions that enhance reliability and reduce losses during permanent magnet recycling (Kapustka et al., 2020).

The fourth study found that the most critical risks were associated with process stages requiring extensive human intervention, particularly the computer-aided design (CAD) of the prosthetic socket and the manual post-processing phase. The most frequent problem identified was an improperly fitted socket, either excessively loose or overly tight, directly affecting patient comfort and prosthesis functionality. The analysis revealed that operator-defined parameters, such as offset values, frequently resulted in fitting failures. In addition, the absence of standardized procedures during manual finishing increased process variability. The authors emphasized the need to reduce dependence on individual expertise by introducing greater automation during the digitalization and modeling stages, as well as establishing objective criteria for fitting adjustments and internal liners. Although minor errors were generally classified as presenting low or medium risk, the critical stages require improved parametric models and larger patient databases to develop more robust predictive algorithms. The study concluded that PFMEA is a feasible methodology for customized medical devices, contributing to reduced risks and rework, although additional clinical cases are required for broader validation (Górski et al., 2022).

The fifth study showed that failures such as electrical winding short circuits, excessive pressure within plate heat exchangers, communication failures in the SCADA system, insulation failures in storage tanks, balance tank lever failures, defective sealing gaskets, perforated heat exchanger plates, feed pump cavitation, and milk residue accumulation in pipelines were classified as the most critical risks. The proposed model demonstrated superior performance compared with conventional PFMEA by assigning different weights to severity, occurrence, and detection, and by accounting for the relative expertise of specialists, thereby reducing subjective bias. Comparisons with the TOPSIS and VIKOR methods confirmed the consistency of the proposed approach, with more than half of the failure modes receiving identical classifications across the different methodologies. The authors concluded that practical implementation of the model could reduce unexpected failures, improve system availability, and increase the reliability of milk pasteurization processes (Das, Panchal, & Tyagi, 2022).

The sixth study demonstrated that the proposed methodology substantially improves the efficiency of process failure mode identification while reducing reliance on lengthy, subjective expert discussions. The model successfully extracted and standardized more than 2,000 process instructions, generating a Process Constituent Element (PCE) library containing over 10,000 validated terms. Similarity analysis based on Natural Language Processing (NLP) enabled systematic and comprehensive identification of potential failure modes, achieving average precision and recall rates exceeding 85% in case studies involving aircraft rudder assembly, flexible fuel tank manufacturing, and landing gear production. Although identification accuracy for resources and process inputs was slightly lower because of semantic variability, the methodology proved both consistent and highly reproducible. The study concluded that automated failure identification is technically feasible and can reduce costs, shorten analysis time, minimize rework, and contribute to the robustness of intelligent manufacturing systems (Wu et al., 2022).

The seventh study demonstrated that Monte Carlo simulation provides a more robust framework for managing uncertainty in FMEA evaluations. In the first case study, involving ion-etching defects and abnormal chemical-etching times, the probability of High Action Priority (AP-H) exceeded 95%. In contrast, the corresponding RPN value (96) indicated a low risk and no corrective action, highlighting a significant discrepancy between the two approaches. In the second case study, involving gas leakage and equipment detection failures, the RPN value was relatively high (108). At the same time, the probability of AP-H remained below 3%, with Low Action Priority (AP-L) exceeding 90%. These findings demonstrate that traditional RPN-based assessments may lead to inappropriate prioritization decisions. By contrast, the probabilistic Monte Carlo approach provided greater transparency and reliability, enabling FMEA teams to allocate resources more effectively in high-risk scenarios (Sun, Yeh, & Pai, 2022).

The eighth study demonstrated that the revised PFMEA approach not only identifies potential failure modes but also directly supports the design of Design-Job Element Sheets (D-JES), equipment, and assembly line layouts during the product development stage. The case study focused on the access door of railway freight wagons, a safety-critical component for both operators and end users. More than 200 potential failure records were identified, leading to the definition of 91 corrective actions, including torque specifications, appropriate tool selection, and compatible lubricant recommendations. The resulting D-JES documents consolidated this information into operator-friendly modules supported by diagrams, layouts, and visual instructions. The study showed that implementing D-JES reduced assembly-related risks, improved process efficiency, and facilitated the training of new operators. Furthermore, integrating PFMEA with D-JES transformed PFMEA from a perceived bureaucratic requirement into a practical engineering tool for the reliable design of complex manufacturing systems (Braglia et al., 2021).

The ninth study demonstrated that conventional Process Failure Mode and Effects Analysis (PFMEA) presents limitations when different failure modes receive identical Risk Priority Number (RPN) values, making effective prioritization difficult. The integration of DEMATEL enabled the identification of the most influential failure modes (FM2, FM3, FM5, and FM9), resulting in a significant reduction in defective products. The Extended Risk Priority Number (ERPN) further enhanced the analysis by incorporating both internal and external failure costs, providing a more economically realistic prioritization. When the three approaches were compared, the conventional PFMEA achieved the smallest reduction in defects. In contrast, DEMATEL produced the fewest defective parts, and ERPN yielded the lowest average RPN while offering greater economic transparency. The study concluded that the proposed hybrid model overcomes the limitations of conventional PFMEA by providing not only a more robust technical assessment but also an economic perspective that supports strategic decision-making in financially constrained industrial environments (Bujna et al., 2023).

The tenth study demonstrated that integrating PFMEA, the Analytic Hierarchy Process (AHP), compensation operators, and denoising techniques significantly improved the accuracy of quality prediction. Hierarchical analysis identified the exposure process (C7), chemical etching (C11), and film coating (C2) as the most critical production stages. The proposed compensation operators successfully eliminated data distortions, such as rework rates exceeding 2.3% and coating thickness variations outside the acceptable range of 110–120 mm, thereby reducing the influence of extreme observations. The denoising operator effectively smoothed high-frequency fluctuations while preserving the underlying structural trends. The resulting Discrete Grey Prediction Model (DGM (1,1)) achieved prediction accuracies exceeding 95%, substantially reducing both residual and relative prediction errors compared with untreated datasets. Short-term forecasting remained stable across the analyzed time series, enabling early detection of potential quality failures. The study concluded that integrating PFMEA with advanced data-processing techniques and Grey System Theory represents a significant advancement in quality prediction for complex manufacturing systems, particularly in the semiconductor industry (Li, Liu, & Lin, 2023).

The eleventh study found that the FRADAR model provided a more accurate and practical prioritization of failure modes. The highest-priority failure was fabric tearing during sewing (i = 12), followed by skipped stitches (i = 3), seam misalignment (i = 1), and thread breakage (i = 2). Conversely, failures such as excessive thread waste (i = 14) and needle damage (i = 4) received the lowest priority because of their relatively limited operational impact. Comparisons with traditional prioritization methods revealed substantial differences: some failure modes classified as high priority by the Action Priority (AP) approach, such as needle breakage, received low priority under FRADAR because corrective actions were not cost-effective. Furthermore, discrepancies between FRADAR and conventional RPN rankings demonstrated that incorporating additional criteria, including implementation cost and production impact, significantly alters failure prioritization. The study concluded that the proposed methodology provides greater rationality and flexibility in prioritizing failure modes while acknowledging that reliance on expert judgment and the computational complexity of fuzzy methods remain important limitations (Komatina et al., 2025).

The twelfth study demonstrated that the proposed EBRT-PFMEA template identified 75 high-risk failure modes among more than 1,400 potential failures, with the treatment delivery (29.3%), treatment planning (24.0%), and imaging acquisition (18.7%) stages representing the highest-risk processes. Preventive and detection controls primarily relied on standardized checklists, institutional procedures, and the four-eyes principle. Regarding failure prioritization, the conventional Risk Priority Number (RPN) required an average of 3.6 corrective actions per failure, whereas the AIAG Action Priority (AP) approach reduced this to 1.7. The proposed Radiation Oncology Action Priority (RO AP) method demonstrated greater flexibility, requiring between 1.3 and 3.5 corrective actions per failure, depending on the adopted weighting scheme, while successfully reproducing AIAG AP behavior after calibration. The study concluded that standardized PFMEA templates can improve the consistency of risk assessment practices in radiotherapy and that the RO AP model represents an important advancement by enabling transparent adaptation to different failure-classification systems (Kornek & Bert, 2024).

The thirteenth study found that the transition from ISO/TS 16949 to IATF 16949 required substantial modifications to organizational quality management systems. The most significant changes included: (i) broader risk analyses based on PFMEA incorporating lessons learned from recalls and customer complaints; (ii) implementation of whistleblowing channels and corporate ethics policies to strengthen corporate responsibility; (iii) systematic monitoring of maintenance indicators such as MTBF, MTTR, and Overall Equipment Effectiveness (OEE) within the Total Productive Maintenance framework; and (iv) formal supplier selection, auditing, and monitoring policies, including directed-buy situations. Companies also reported challenges associated with controlling temporary process changes, managing reworked and repaired products, and conducting audits across multiple production shifts. Nevertheless, organizations experienced improvements in process standardization, supply chain reliability, and overall organizational performance. The study concluded that implementing IATF 16949 extends well beyond regulatory compliance, representing a cultural transformation that requires strong top management commitment and effective cross-functional integration (Bozola et al., 2023).

The fourteenth study demonstrated that the proposed integrated methodology effectively reduced risks and prevented experimental failures. Seven of the eight experiments were completed without incidents, while the single occurrence was rapidly detected and mitigated without compromising operational safety. The use of digital Coversheets incorporating green, yellow, and red status indicators enabled real-time monitoring and allowed experimental activities to be interrupted whenever risk levels reached critical thresholds. The researchers identified 16 physical risks, 16 environmental risks, and 32 quality-related risks, all of which were classified and monitored through integrated HAZOP and PFMEA analyses. Combining these methodologies provided a comprehensive assessment of potential failures by simultaneously addressing occupational safety, environmental impact, and experimental quality. The study concluded that the methodology requires no significant additional investment, as it relies on widely available spreadsheet software. It recommended its implementation in other academic and industrial laboratories to strengthen organizational safety culture (Silva et al., 2020).

The fifteenth and final study demonstrated that the proposed modified Fuzzy PFMEA model provides a more realistic assessment of the influence of risk factors on process quality. Among the identified risk factors, layer thickness (w1), design capability (w4), and operational capability (w5) exerted the greatest influence. The failure mode "dimensions outside tolerance" was consistently identified as the most critical across all manufacturing workshops and was recognized as the key quality characteristic. The application of the value-risk matrix showed that Workshop 4 combined high-quality performance with high-risk exposure, requiring continuous monitoring. In contrast, Workshops 2 and 3 demonstrated high quality with relatively low risk, indicating the need for only preventive actions. In contrast, Workshops 1 and 5 occupied higher-risk quadrants, requiring contingency planning. The proposed model also translated risk assessments into Six Sigma performance metrics, revealing reductions in sigma levels under high-impact scenarios. Sensitivity analysis confirmed the robustness of the methodology with respect to variations in factor weights. The study concluded that integrating Fuzzy PFMEA, the Analytic Network Process (ANP), and Six Sigma metrics provides greater accuracy for strategic decision-making while aligning quality management practices with the requirements of ISO 9001:2015 and the principles of Quality 4.0 (Kar & Rai, 2025).

4. RESULTS ANALYSIS

This section provides a detailed discussion of the main findings obtained from the bibliometric review and qualitative analysis of the 15 selected studies on Process Failure Mode and Effects Analysis (PFMEA). The analysis is structured around the evolution of publications, identified methodological advances, sector-specific contributions, observed limitations, and practical and academic implications.

The results presented reflect evidence synthesized from recent studies, including Yousefi, Rezaee, and Moradi (2020), Zeng, Shao, and Hao (2021), Górski et al. (2022), and Das, Panchal, and Tyagi (2022), among others. This body of evidence provides insight into how PFMEA has been applied, improved, and expanded within the context of Production Engineering and the transformations associated with Industry 4.0.

4.1 Evolution and Overview of Publications

The first aspect analyzed concerns the quantitative overview of PFMEA publications, including their temporal evolution, predominant application areas, and document types. These aspects provide insight into how interest in this methodology has evolved across different academic and industrial contexts.

Figure 1 shows that publications related to PFMEA have increased steadily since 2016, with a more pronounced growth after 2019. Studies by Das, Panchal, and Tyagi (2022), Zeng, Shao, and Hao (2021), and Wu et al. (2022) corroborate this trend, indicating that the growing demand for greater reliability, automation, and digital integration has driven the adoption of PFMEA over the past decade.

Figure 2, which illustrates the main application areas, reveals the predominance of engineering disciplines, particularly manufacturing and automotive contexts, as reported by Bozola et al. (2023), Komatina et al. (2025), and Bujna et al. (2023). However, the still limited presence of PFMEA in fields such as healthcare and services highlights opportunities for methodological expansion. In healthcare settings, for example, process failure analysis can directly contribute to patient safety, as demonstrated by Górski et al. (2022), Kornek and Bert (2024), and Silva et al. (2020). Although the wide variety of applications across sectors reflects the methodology's versatility, it also supports the observations of Braglia et al. (2021) and Wu et al. (2022) that the existing literature would benefit from greater systematization.

Figure 3 indicates that the majority of publications are journal articles and conference papers, underscoring the vitality of applied research in this field (Bozola et al., 2023; Wu et al., 2022). The relatively small number of systematic review studies further emphasizes the importance of the present work, which seeks to critically synthesize and analyze the existing body of knowledge on PFMEA, addressing a need also identified by Braglia et al. (2021) and Komatina et al. (2025).

Overall, the publication trends indicate that PFMEA has gained increasing prominence in recent years, driven by evolving industry standards and the technological advancements associated with Industry 4.0. At the same time, the concentration of studies within a limited number of application areas highlights the need to expand its use into sectors that remain relatively underexplored, such as healthcare, as demonstrated by Górski et al. (2022), and material recycling, as investigated by Kapustka et al. (2020).

4.2 Objectives and Methods of the Reviewed Studies

In addition to the increasing number of publications, it is also important to examine the research objectives and methodologies employed in the reviewed articles (Table 1). This analysis provides insight into how researchers have applied PFMEA, the methodological approaches they have preferred, and how these choices influence the reliability of their findings.

Table 1 reveals two primary research directions: the application of PFMEA in specific contexts and the proposal of methodological improvements. This finding indicates that, while PFMEA has become a well-established technique, considerable efforts continue to modernize and adapt it to meet the evolving demands of contemporary industry (Braglia et al., 2021; Wu et al., 2022).

The reviewed methodologies also demonstrate a clear trend toward integrating PFMEA with complementary analytical tools. Among the most frequently adopted approaches are fuzzy logic (Komatina et al., 2025; Kar & Rai, 2025), which addresses uncertainty in expert judgments; DEMATEL, used to analyze cause-and-effect relationships (Bujna et al., 2023); and multicriteria decision-making methods such as TOPSIS and VIKOR (Das, Panchal, & Tyagi, 2022), which seek to replace or complement the traditional Risk Priority Number (RPN). This trend is consistent with the criticism presented by Braglia et al. (2021), who identified mathematical and logical limitations in the conventional RPN approach. Overall, the analysis highlights both the diversity of PFMEA applications and the ongoing efforts to overcome its limitations, particularly through integration with multicriteria decision-making methods and computational intelligence techniques (Das, Panchal, & Tyagi, 2022).

4.3 Main Findings of the Reviewed Studies

Based on the synthesis presented in Table 2, the principal theoretical and practical contributions of the reviewed studies can be identified. This stage demonstrates how recent research has expanded scientific knowledge on PFMEA by proposing methodological advances and illustrating relevant applications across diverse industrial and organizational contexts. It also highlights emerging trends and research gaps that may guide future investigations in this field.

The reviewed studies can be grouped into three main categories: methodological advances, organizational impacts, and emerging research trends. Regarding methodological advances, the literature reveals an increasing integration of PFMEA with quantitative techniques such as fuzzy logic (Komatina et al., 2025; Kar & Rai, 2025) and Monte Carlo simulation (Sun, Yeh, & Pai, 2022), as well as qualitative methods such as DEMATEL (Bujna et al., 2023), resulting in more accurate and less subjective analyses.

Regarding organizational impacts, the studies report significant benefits across sectors, particularly in the automotive industry and heavy maintenance operations (Bozola et al., 2023; Bujna et al., 2023). In these contexts, PFMEA helped reduce critical failures and support strategic reliability decisions while ensuring compliance with standards such as IATF 16949. In the healthcare sector, the studies by Kornek and Bert (2024) and Silva et al. (2020) further demonstrate PFMEA's contribution to patient safety and the reliability of laboratory processes.

Regarding emerging research trends, the literature indicates a growing convergence between PFMEA and Industry 4.0 concepts, particularly digitalization and data analytics (Wu et al., 2022; Li, Liu, & Lin, 2023), suggesting that the methodology is being reinterpreted to address new technological challenges. Despite this progress, most reported applications remain concentrated in manufacturing. In contrast, sectors such as healthcare, energy, and services remain underrepresented, creating opportunities for future research in high-risk environments beyond traditional industrial settings.

Overall, the findings confirm PFMEA as an important methodology for improving process reliability while revealing clear trends toward methodological innovation. However, the diversity of research topics and methodological approaches suggests that further efforts are needed to consolidate and expand knowledge across sectors beyond manufacturing, thereby broadening the methodology's scope and applicability.

5. CONCLUSIONS

The present study aimed to critically analyze the applications and methodological advances of Process Failure Mode and Effects Analysis (PFMEA) across different industrial and organizational contexts, identifying how recent approaches have enhanced the identification, prioritization, and mitigation of risks in manufacturing and service processes. Based on the literature review, the main trends and the theoretical and practical contributions associated with PFMEA in the context of Industry 4.0 were identified.

The findings demonstrate that PFMEA has continued to evolve and consolidate its role as an essential tool for process reliability and risk management within Industry 4.0. The bibliometric and qualitative review revealed a consistent increase in scientific interest, reflecting the growing demand for more effective methods to anticipate failures and support continuous improvement initiatives.

The results also indicate that PFMEA is undergoing a significant transformation, evolving from a predominantly standards-driven methodology into an integral component of intelligent decision-support systems. Recent literature highlights increasing integration of quantitative methods and digital technologies, expanding their applicability and contributing to more accurate, reliable, safe, and efficient production processes.

The primary contribution of this study is a consolidated overview of current trends and research gaps in PFMEA, providing a valuable foundation for future academic investigations and practical applications. Furthermore, the findings emphasize the potential of PFMEA to support organizations in their transition toward Quality 4.0 by integrating risk analysis, technological innovation, and information management into a comprehensive decision-making framework.

Nevertheless, the analysis also reveals that the existing scientific literature remains largely concentrated in traditional industrial sectors, highlighting opportunities to expand PFMEA applications into areas such as healthcare, services, and sustainability. Future research should investigate integrating PFMEA with artificial intelligence and real-time data analytics to strengthen its relevance in the digital era.

In conclusion, PFMEA remains a fundamental methodology in Production Engineering for achieving quality improvement and failure prevention. However, its continued evolution will depend on its ability to adapt to emerging technological and organizational challenges, reinforcing its role as a strategic tool for decision-making and industrial competitiveness.

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