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Synergizing FMEA and PDCA for superior risk management and process improvement in the semiconductor industry: a case study

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Abstract:

The semiconductor industry faces the dual challenge of risk assessment and process improvement. This paper introduces a framework that integrates Failure Mode and Effects Analysis (FMEA) and Plan-Do-Check-Act (PDCA) cycle to address these challenges effectively. FMEA serves as the initial step to identify potential risks within the system, followed by applying the PDCA cycle to systematically address and enhance the identified risks. The comparison between the initial Risk Priority Number (RPN) value, determined through FMEA, and the post-RPN in PDCA value gauges the success of the framework. Implementing the system in a semiconductor assembly line yielded a significant 51% improvement in RPN, with additional Lean tools incorporated into PDCA, such as SMART goals, 6M, and multi-voting. This integrated framework amplifies risk management, fosters continuous improvement, optimizes resource utilization, and empowers data-driven decisions, ultimately bolstering organizational growth. However, the study acknowledges limitations such as its single-case focus and potential RPN calculation subjectivity.

Key words:

FMEA, PDCA, risk assessment, process improvement, semiconductor industry.

1. Introduction

As the semiconductor industry evolves, it remains a crucial pillar supporting our modern technological ecosystem. This sector crafts the essential components that drive the functionality of the electronic devices integral to our daily lives. Companies in this industry face growing pressure to consistently innovate and develop new products (Chivukula & Pattanaik, 2023). This imperative arises from the increasing demands of consumers and the competitive nature of the market. To stay relevant and sustain their businesses, these companies must continuously research and create cutting-edge solutions that meet the evolving needs of the tech-driven world (Koteswarapavan & Pattanaik, 2024). In essence, the semiconductor industry stands at the forefront of technological progress, shaping the innovation landscape and influencing the trajectory of global connectivity and communication (Petricevic & Teece., 2019).

Various risks in the semiconductor industry impact operations and market standing. The intricate manufacturing processes for semiconductor components are vulnerable to disruptions, such as equipment malfunctions or quality control issues, leading to production delays and potential defects (Zarreh et al., 2019). Supply chain vulnerabilities are a significant concern as the industry relies on a global network of suppliers. Disruptions in the supply chain, including geopolitical tensions or unexpected shortages, can impede production schedules and raise costs (Akhtar, 2023). Semiconductor manufacturers mitigate these risks through contingency planning, supplier diversification, and monitoring geopolitical developments. Technological uncertainties pose

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another challenge, requiring constant investment in research and development to stay competitive. However, this entails the risk of investing in technologies that may become obsolete or face unexpected obstacles. Effective risk assessment involves balancing innovation with adaptability to changing technology trends. Market dynamics and fluctuations present additional challenges due to the nature of the industry. Influenced by global economic conditions and consumer demand, manufacturers navigate uncertainties by diversifying products, building strong customer relationships, and maintaining financial flexibility to withstand market downturns. Proactively managing these challenges enables semiconductor manufacturers to thrive in a dynamic and competitive environment (Ishak et al., 2023).

FMEA is vital for proactive risk assessment in semiconductor industry. FMEA systematically identifies potential failure modes, evaluates their consequences, and prioritizes risks based on severity, occurrence, and detection (Ivančan & Lisjak., 2021). This approach proves essential in addressing the intricate processes of semiconductor industry, helping mitigate risks associated with equipment malfunctions, process deviations, and quality control issues. Additionally, FMEA enhances supply chain management by identifying vulnerabilities related to geopolitical tensions and material shortages, enabling semiconductor manufacturers to implement effective contingency plans and supplier diversification. Integrating FMEA into risk assessment processes enhances operational excellence and competitiveness in the dynamic semiconductor industry (Cabanes et al., 2021).

The popularity of the FMEA stems from its effectiveness in early-stage risk elimination, but it tends to become uncontrolled and lacks proper documentation. Consequently, there is a pressing need for a plan to manage project data comprehensively (Sari1 et al., 2019). The current study compares the effectiveness and data control of the traditional FMEA and a systematic database design system for FMEA. The traditional FMEA, involving manual recording in spreadsheets with separate ratings for each project, struggles to keep up with the rapid product development pace that many global companies today demand. This manual approach leads to time inefficiencies, redundant ratings for the same issues, and potential oversight of critical issues due to human error. The users face challenges in retracing issues from past projects for reference in new product development with similar modules, further hindering efficiency (Windheim, 2020).

In the semiconductor industry, PDCA is crucial for diverse applications. It systematically refines manufacturing processes, ensuring product quality and driving innovation in research and development. Its structured approach is a problem-solving methodology, addressing issues and preventing recurrence. PDCA is integral for risk management, allowing companies to plan for and mitigate potential risks. In the context of complex supply chains, it optimizes processes through planning, execution, monitoring, and adjustment (Serrano-Ruiz et al., 2021). PDCA fosters a culture of continuous improvement, adaptability, and operational excellence within semiconductor companies. When resolving non-critical problems, resource misallocation is risky when using the PDCA.

In some cases, organizations may apply PDCA to problems that, upon closer examination, prove inconsequential or have minimal impact on overall operations. This misalignment of effort and resources can lead to inefficiencies, as the structured PDCA may be overly rigorous for less critical issues. It becomes a potential waste of time and resources when the level of scrutiny and intervention provided by PDCA exceeds the importance or urgency of the problem being addressed (Dixon-Woods, 2019). Therefore, careful prioritization of issues is essential to maximize the effectiveness of PDCA.

The existing literature predominantly focuses on the standalone applications of FMEA and PDCA, recognizing their merits in risk mitigation and continuous improvement. However, the synergistic integration of these tools remains underexplored in academic research. FMEA excels in preemptively identifying potential failure modes and associated risks, while PDCA provides a structured approach for continuous improvement through planning, execution, monitoring, and adjustment. By examining their integration, this research aims to uncover novel and enhanced methodologies that harness the complementary strengths of FMEA and PDCA, potentially offering a more comprehensive and effective approach to risk management and continuous improvement in various industry contexts (Moreira, 2022).

The literature demonstrates diverse applications of integrating PDCA and FMEA across different industries. Yuswardi & Boonyoung (2012) review centers on patient safety in nursing, emphasizing the integration of PDCA and FMEA for quality improvement. It explores harm from potential risks, hospital dimensions for safety enhancement, and tools like PDCA and FMEA in achieving patient safety and care quality. Ebeid et al. (2016) emphasize the significance of maintenance management and integrate Lean Maintenance and Maintenance Excellence into a Lean Maintenance Excellence framework. It incorporates Reverse FMEA and the traditional PDCA, resulting in a 73% reduction in the preventive maintenance cost of the tractors and identifying 27.7% of engine breakdown causes. Mielczarek & Smolarek (2017) examine the manufacturing process of unit packaging in a printing enterprise, employing a Pareto-Lorenz diagram to identify disagreement structure. FMEA classifies disagreement causes, and analysis results focus on quality improvement methods, integrating the Deming cycle, PDCA, and the SDCA cycle to meet customer requirements effectively. Dewi et al. (2022) employ Six Sigma with the PDCA to enhance the production process and minimize defects. Initial stages include defining Critical to Quality and prioritizing product improvements. The analysis incorporates FMEA, and improvements are proposed through the PDCA, resulting in a 0.4 increase in the sigma value to 3.1.

The current challenge lies in integrating FMEA and PDCA, particularly in identifying critical problems and enhancing overall risk management. FMEA and PDCA, when used independently, can miss key issues. To address this, integrating FMEA as risk identification with PDCA as a problem-solving approach would significantly improve both risk management and continuous improvement efforts. Another gap is in the practical implementation and real-world application of this integration, especially in the semiconductor industry. Although theoretical discussions on the benefits of FMEA and PDCA are common, there is a lack of empirical studies and case examples demonstrating successful integration in various industries. Insufficient exploration into the practical challenges, lessons learned, and best practices of merging FMEA with PDCA hampers the provision of actionable insights. Bridging this gap would not only strengthen the theoretical foundation but also offer practical guidance for organizations looking to enhance their risk management and continuous improvement processes.

To address the identified gap in integrating FMEA and PDCA, our research focuses on developing a system design tailored for FMEA. This innovative system aims to streamline and enhance the effectiveness of project management, offering users significant time savings. The ultimate goal is to minimize the risks associated with potential product or module failures, ensuring higher quality and customer satisfaction.

The paper follows a structured format with several chapters: Chapter 2 provides a literature review on FMEA and PDCA, existing systems, and prior research. In Chapter 3, the methodology is outlined. Chapter 4 elaborates on the integration of the FMEA-PDCA system. Chapter 5 presents a case study, including company background and system implementation. Chapter 6 discusses the findings. Lastly, Chapter 7 concludes the paper by summarizing key points.

2. Literature review

2.1. FMEA

FMEA is a systematic process analysis tool that began in the 1940s by the US military and later became widely adopted by the automotive industry to help engineers assess and mitigate potential failure modes and design risks. FMEA is a typical structured and proactive approach to analyzing product or system failure (Xu et al., 2020). FMEA has been applied throughout the industries to prevent problems or issues in processes and products. FMEA can help to reduce failure and costs by managing the risks or identifying the risks in the product development stage (McDermott et al., 2009). FMEA is also known as bottom-up inductive system analysis, which analyzes potential errors, including finding the root cause and how the error occurs (Ramere & Laseinde, 2021). It is implemented by identifying themes, forming a functional team, drawing flowcharts, conducting a hazard analysis, and implementing continuous improvement or corrective action. It is a potential hazard prediction technology that combines a person's or team's theory and experience (Chen et al., 2022).

FMEA systematically identifies potential failure modes, assesses their impact, and prioritizes preventive actions, leading to enhanced decision-making and proactive risk mitigation. FMEA improves product and process reliability, reduces costs, and increases customer satisfaction across diverse industries (Sharma & Srivastava, 2018). By offering a structured framework for anticipating and addressing potential failures, FMEA becomes essential for organizations striving for operational excellence and continuous improvement in their operations, ultimately ensuring higher product and service quality.

FMEA finds versatile applications across manufacturing, healthcare, automotive, aerospace, and beyond industries (Elangovan, 2021). In manufacturing, FMEA is employed to enhance product quality and production processes. In healthcare, it ensures patient safety and quality care. The automotive industry uses FMEA to improve vehicle design and reliability. Aerospace applications focus on safety and reliability in aircraft systems. The adaptability of FMEA extends to various sectors, providing a systematic methodology for identifying, prioritizing, and mitigating risks, ultimately contributing to enhanced product quality, process efficiency, and overall organizational performance.

FMEA involves systematic steps to identify failure modes in a system, product, or process (Sharma & Srivastava, 2018). Subsequently, each failure mode undergoes assessment for its potential impact on safety, functionality, and customer satisfaction. The team then delves into analyzing the root causes of each failure, followed by an evaluation of existing preventive measures. The ability to detect failure modes before reaching the end user is assessed, considering testing and monitoring mechanisms. The process concludes with calculating the Risk Priority Number (RPN) by multiplying severity, occurrence, and detection scores as in Equation 1, guiding prioritization for addressing failure modes (Anes et al., 2018).

$$RPN = \text{Severity} \times \text{Occurence} \times \text{Detection} \quad (1)$$

Severity in the RPN calculation assesses the potential impact of a failure mode on safety, functionality, and customer satisfaction. Occurrence evaluates the likelihood of the failure, considering its frequency in the system. Detection measures the effectiveness of controls in identifying and preventing the failure before it reaches the end user. Severity, occurrence, and detection are typically measured on a numerical scale of 1 to 10, as listed in Table 1. Higher RPN values indicate a greater need to address the associated failure modes to enhance overall system, product, or process reliability. These scales are subjective and may be adapted based on the organization's preferences or industry standards. The key is ensuring consistency in applying these ratings across the FMEA analysis team. The cumulative multiplication of severity, occurrence, and detection scores results in the RPN prioritizing potential failure modes for corrective actions (Shi et al.,2020).

The FMEA table, as shown in Table 2, serves as a structured documentation tool, systematically recording and visually representing information related to failure modes, causes, effects, and the effectiveness of controls, enabling cross-functional teams to analyze and prioritize potential risks collaboratively (Michalakoudis, 2019). It consolidates quantitative and qualitative data, facilitating the computation of the RPN and ensures traceability for tracking risk mitigation progress over time. The table acts as a communication tool, conveying complex information to stakeholders, and provides a documented record for future reference, audits, and continuous improvement efforts within diverse industries.

Some organizations may set internal guidelines or thresholds for RPN values, designating specific

Table 1. Scale for RPN factors: severity, occurrence, and detection.

RPN factors	Range	Description
Severity Scale	1 - 3	Negligible impact, a slight inconvenience
	4 - 6	Moderate impact, manageable consequences
	7 - 9	Profound impact, significant consequences
	10	Critical impact, severe consequences, including safety hazards
Occurrence scale	1 - 3	Rare occurrence
	4 - 6	Occasional occurrence
	7 - 9	Frequent occurrence
	10	Almost certain occurrence
Detection Scale	1 - 3	Very likely to detect
	4 - 6	Likely to detect
	7 - 9	Unlikely to detect
	10	Very unlikely to detect

Table 2. FMEA Table.

Failure mode	Effect of failure	Severity (1-10)	Causes of the failure	Occurrence (1-10)	Current action	Detection (1-10)	RPN

ranges as low, moderate, or high risk. An RPN value exceeding a particular limit might trigger immediate corrective actions, while values below that threshold may be monitored or addressed as part of routine maintenance. For instance, an organization might designate RPN values exceeding 200 as high risk, triggering immediate corrective actions. This approach ensures a swift response to critical failure modes that have the potential for severe consequences. In cases where RPN values fall between 100 and 200, organizations may categorize this as moderate risk, prompting close monitoring and implementing preventive measures during routine maintenance or periodic reviews. This allows for a proactive stance in managing risks without necessitating immediate corrective actions. Organizations may consider failure modes with RPN values below 100 low risks, permitting routine maintenance practices and periodic reviews to keep risks at acceptable levels (Hall, 2017).

2.2. PDCA

PDCA, or the Deming cycle, is a renowned Lean Manufacturing from the 1930s. Initially conceived by Walter A. Shewhart, William Edward Deming further developed it in the 1950s, gaining global application (Realyvásquez-Vargas et al., 2018). Representing Plan, Do, Check, Act, PDCA involves planning, implementing, inspecting, and processing stages. In the actual working stage, these four stages can be carried out simultaneously or successively to analyze or find out the causes of the problems (Kurnia et al., 2020). The process is then summarized and brought forward to the next cycle, which can be concluded as an effective management style of continuous improvement (Ho Song & Fischer, 2020). Hence, PDCA is a universal and practical management philosophy (He et al., 2020). This scientific and standard management procedure was first used in enterprise management and managed to get good results (Usman & Windijarto, 2019). Due to its thorough operating procedures and application in various management levels, PDCA can be applied to different types of management. Industries worldwide adopt it as a suitable and effective method to enhance management, processes, and products (Ruzicic & Micic, 2020).

PDCA emphasizes addressing problems without presupposing solutions—the phases of PDCA are shown in Figure 1. The planning process involves setting specific, measurable, achievable, relevant, and time-bound (SMART) goals —and devising a comprehensive plan to achieve them. Moving to the "Do" phase, the focus shifts to implementation (Patfield et al., 2023). The plan, carefully crafted in the preceding phase, is executed on a small scale. This allows organizations to test the changes in a controlled environment, facilitating data collection and identifying potential challenges. The Do phase acts as a practical experiment, providing real-world insights into the effectiveness of the proposed solutions (Gray, 2021). Following implementation, the "Check" phase involves a critical evaluation of the outcomes. Organizations compare the actual results against the expected ones, relying on data collected during the "Do" phase. This analysis serves to determine whether the changes have led to improvement and if they are sustainable in the long run. During this phase, the iterative nature of PDCA becomes evident as the results guide the subsequent actions. The final step, "Act," involves taking action based on the evaluation. If the results align with expectations, the changes are standardized and implemented on a broader scale. Conversely, if the results fall short, a detailed analysis is conducted to refine the plan, and the cycle restarts. This continuous loop of planning, doing, checking, and acting ensures that organizations remain adaptable

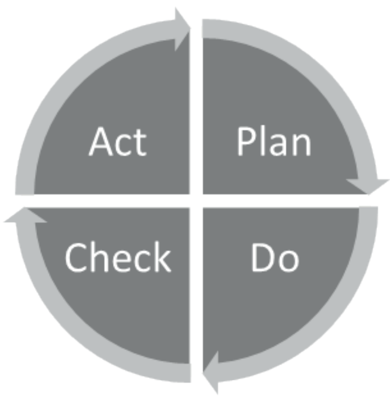


Figure 1. PDCA cycle (Kurnia et al., 2022).

and responsive to evolving challenges, fostering a culture of perpetual improvement (Protzman et al., 2022).

Lean tools seamlessly integrate with the PDCA cycle, providing a structured approach to continuous improvement (Thakur et al., 2023). In the Plan phase, SMART goals, Fishbone diagrams, and Multi-Voting guide strategic planning. The Do phase leverages Kaizen principles for incremental changes and Poka-Yoke techniques for error prevention. Moving to the Check phase, statistical tools like Control Charts and analytical methods such as Histograms and Pareto Analysis assess outcomes. Lean tools like Standard Work and Gemba Walks standardize improvements and foster ongoing refinement in the Act phase. This harmonious integration ensures a systematic and effective journey through problem identification, solution implementation, evaluation, and standardization.

2.3. The existing literature on the integration of FMEA and PDCA

The integration of FMEA and PDCA methodologies offers a compelling avenue for enhancing quality management, risk mitigation, and organizational performance across diverse industries. Existing literature provides valuable insights into the individual application of FMEA and PDCA, showcasing their efficacy in addressing specific challenges and streamlining processes. However, a comprehensive examination of their integrated use as a cohesive system for quality improvement and risk management is notably absent. This gap in the literature underscores the need for further research to explore the synergies between FMEA and PDCA and develop best practices for their combined implementation.

Mohan et al. (2012) present a case study on implementing Quality Circles in educational institutes, where FMEA and PDCA are integral to a holistic problem-solving approach. Identifying “Improper laboratory conditions” as a key issue, the study employs multi-dimensional problem analysis tools, including process flow and Fishbone diagrams, to uncover root causes. Solutions are then executed using a milestone chart supported by FMEA and PDCA. This case study illustrates the positive impact of integrating FMEA and PDCA methodologies on operational efficiency and student growth in educational institutes.

Yuswardi & Boonyoung (2012) focus on patient safety in nursing, utilizing PDCA and FMEA to enhance care quality and integrate risk management practices. The study emphasizes the importance of fostering a safety culture and employing various research methods and tools to ensure patient safety. While primarily emphasizing the individual application of PDCA and FMEA, this study underscores the potential benefits of integrating these methodologies into a unified approach to tackle complex healthcare challenges effectively.

In maintenance management, Ezzat & Ebeid (2017) explore integrating Lean Maintenance and Maintenance Excellence methodologies into a unified framework, incorporating Reverse FMEA and PDCA. The study conducted in a Multinational Container Terminal in Egypt significantly reduces tractor preventive maintenance costs and identifies causes for engine breakdowns. This research exemplifies the synergies between FMEA and PDCA in optimizing maintenance processes and minimizing downtime. Addressing significant losses due to product defects in wood floor and wall panel production, Handoko (2017) implements quality control methods, including PDCA and FMEA. The study results in reduced losses and improved product quality. While primarily focusing on the individual application of PDCA and FMEA, this research highlights their complementary roles in addressing quality management challenges and driving continuous improvement initiatives. Mielczarek & Smolarek (2017) examine the manufacturing process of unit packaging in the printing branch enterprise, utilizing FMEA to classify causes of discrepancies during production. Emphasizing quality improvement methods aligned with the Deming cycle, PDCA, and SDCA cycle of standardization, this study underscores the potential for integrating FMEA and PDCA into quality management systems to meet customer requirements effectively.

Chuah & Lim (2018) discuss the importance of student retention for financially constrained universities and propose a monitoring system to prevent dropouts, integrating FMEA and PDCA from manufacturing into open distance learning. Prioritizing high-impact issues, facilitating cross-departmental collaboration, and ensuring timely completion of studies, this study encourages the broader exploration of academic quality analysis tools. Prasetyani et al. (2019) discuss the significance of maintaining product quality for PT BCCI to compete in the surfactant industry. Using PDCA and FMEA to address machine performance and product temperature, they ultimately improve product quality, aligning with their target. Alfatiyah (2019) discusses the factors causing shoe spoilage, using PDCA and FMEA to overcome the issue and achieve significant improvement after applying the tools and concepts.

Tuháček et al. (2020) introduce an innovative method for evaluating project documentation during the building design phase, focusing on integrating FMEA and PDCA. The research demonstrates the effectiveness of applying FMEA and PDCA in addressing construction defects early in the preparation phase. Chandrahadinata & Nurdiana (2021) deliberate on enhancing crude palm oil production quality using FMEA, PDCA, and Kaizen methodologies, implementing improvement strategies to enhance crude palm oil quality and production processes. Tuháček (2020) address the importance of checking project documentation quality in construction projects, proposing a method based on continuous quality improvement principles, such as the PDCA diagram. FMEA is suggested for analyzing data from monitoring claimed defects, aiming to prevent recurrent defects and achieve financial savings for building companies.

Prasetyo et al. (2021) address high downtime in the PT Tire Manufacturing Indonesia Tbk extruder machine using PDCA, seven tools, and FMEA. Significant improvements are achieved in reducing downtime, highlighting the effectiveness of integrating FMEA and PDCA in optimizing production processes and minimizing losses. Santoso et al. (2021) address product failures like "Black Stain Defects" at PT MPZ, an Indonesian tissue manufacturer, using FMEA and PDCA, focusing on risk management and recommending adjustments to minimize production failures. Syahrullah & Izza (2021) conducted a study to reduce defects in sarong manufacturing, utilizing FMEA alongside PDCA and identifying areas for quality enhancement and monitoring. Wang et al. (2021) discuss a study involving tracheal intubation in children with severe pneumonia, comparing the effects of medications and employing FMEA to investigate unplanned extubating causes, emphasizing the importance of effective monitoring through PDCA.

Chen et al. (2022) discuss the impact of PDCA and FMEA on the work efficiency, teamwork, and self-identity of medical staff, highlighting the positive outcomes of a comprehensive management approach. Dewi et al. (2022) focus on improving production processes and reducing defects using Six Sigma with define-measure-analyze-improve-control (DMAIC), employing FMEA to identify defect factors and suggesting improvement strategies using PDCA. Kurnia et al. (2022) examine declining machine productivity in sock production of the garment industry, utilizing PDCA and FMEA to identify critical causes.

Albana & Dahda (2023) studied quality issues in Boiler Feed Water at PT. Petrokimia Gresik using PDCA and Seven Tools: check sheets, histograms, Pareto diagrams, control charts, Fishbone diagrams, and FMEA. Their approach reduced SO_3 and PO_4 defects by 67.5%, implementing preventive maintenance, standard operating procedure consistency, spare part monitoring, and chemical checks in wastewater.

While existing literature offers valuable insights into the individual applications of FMEA and PDCA across diverse industries, there exists a critical research gap regarding their integrated use, specifically within the semiconductor industry. Despite occasional mentions of integrating these methodologies, a comprehensive exploration of how FMEA and PDCA can synergize to drive continuous improvement and risk management in semiconductor manufacturing processes is notably absent. This gap limits a thorough understanding of how these methodologies can collectively enhance organizational performance and resilience in semiconductor fabrication.

In the semiconductor industry, characterized by rapid technological advancements, stringent quality requirements, and complex manufacturing processes, the need for a systematic approach to quality management and risk mitigation is paramount. FMEA plays a crucial role in identifying potential failure modes in critical processes like lithography, etching, and testing, while PDCA provides a structured framework for implementing improvements based on FMEA findings. However, the specific challenges and intricacies of semiconductor manufacturing, such as process variability, equipment sensitivity, and the high cost of failure, necessitate a tailored integration of these methodologies.

3. Methodology

Literature Review – A thorough literature review is the foundation for integrating FMEA and PDCA. Through thoroughly exploring existing literature, insights into successful integration models and potential pitfalls become apparent. The review should focus on understanding how FMEA and PDCA contribute to risk management and continuous improvement. Identifying synergies between the two methodologies is crucial to creating a cohesive integration strategy. Literature review findings help shape the integration framework, guiding the development of protocols for collaboration and information exchange between FMEA and PDCA teams.

System Development – With insights from the literature review, the next step involves developing a structured system for integrating FMEA and PDCA. This system outlines a systematic approach to combining the strengths of both methodologies. Communication, data sharing, and collaboration protocols are established to ensure seamless integration. Defining transparent processes for risk identification, analysis, and iterative problem-solving is critical. The system development phase also includes creating documentation and guidelines for teams involved in the integrated process. By outlining roles, responsibilities, and the flow of information, this phase sets the stage for a well-coordinated integration effort.

Pilot Run – The integration methodology moves into practical application through a pilot run in a controlled environment. During this phase, teams execute FMEA to identify potential failure modes and then apply PDCA to implement corrective actions. Close monitoring and collecting stakeholder feedback provide valuable insights into the real-world applicability and effectiveness of the integrated approach. The pilot run serves as a testing ground, allowing organizations to validate assumptions made during system development. Lessons learned from this phase inform adjustments to the integration framework, ensuring that the methodology aligns with the organization's specific needs and challenges.

Result Analysis – Following the pilot run, a thorough analysis of results is conducted to evaluate the effectiveness of the integrated FMEA-PDCA methodology. This analysis encompasses identifying successful risk mitigation strategies, the efficiency of problem-solving processes, and any notable improvements in overall organizational performance. Metrics such as time saved, resource optimization, and the ability to address critical risks systematically are assessed. Stakeholder feedback, both quantitative and qualitative, contributes to a comprehensive understanding of the methodology's impact. The result analysis phase provides a basis for informed decision-making regarding the refinement and scaling of the integrated approach.

Iterative Refinement – Continuous improvement is a critical principle in the integration methodology. Based on the results and feedback gathered, the system undergoes iterative refinement. This phase involves adjusting protocols, communication channels, or specific steps within the integrated process to address identified shortcomings. Lessons learned from the pilot run are systematically incorporated, fostering an environment of ongoing enhancement. The iterative refinement ensures that the integration framework remains dynamic and responsive to changing organizational needs and external factors.

Scale-Up Implementation – With the refined integration framework, the methodology moves to a broader scale-up implementation. This phase involves deploying the integrated FMEA-PDCA approach across broader organizational processes. Proper training and communication strategies are implemented to facilitate a seamless transition for all relevant teams. Lessons from the pilot run and iterative refinements inform the scale-up process, ensuring that the integrated methodology aligns with organizational goals, industry standards, and regulatory requirements. Continuous monitoring and feedback mechanisms are established to support ongoing improvement and adaptability.

4. The integration FMEA-PDCA system

The FMEA-PDCA system consists of five phases: Phase 1: Pre-RPN, Phase 2: Plan, Phase 3: Do, Phase 4: Check Post-RPN, and Phase 5: Act, as depicted in Figure 2.

Phase 1: Pre-RPN involves several key steps to systematically identify and assess potential failure modes of the system or process before they occur. Firstly, failure modes are identified and documented, outlining potential scenarios that could compromise system integrity. Then, the pre-severity of each failure mode is evaluated, considering the potential impact

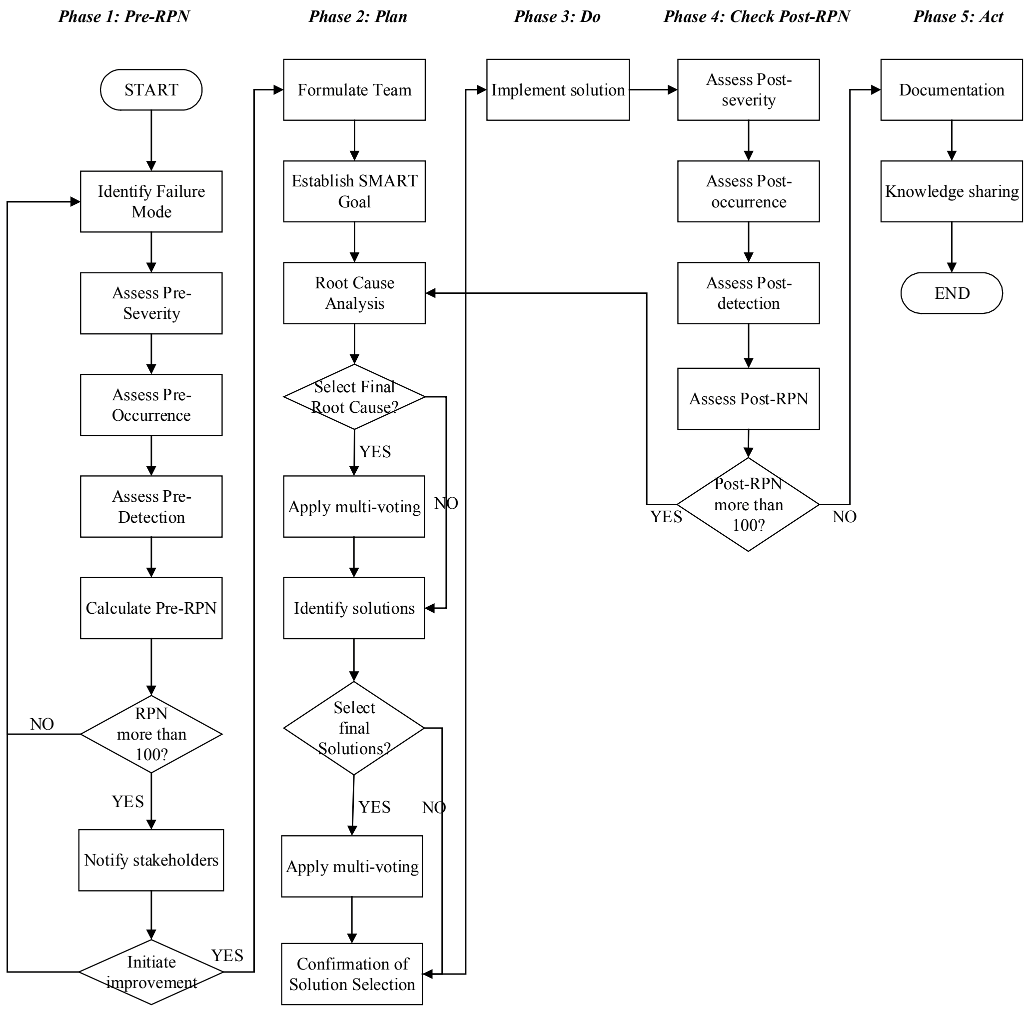


Figure 2. The FMEA-PDCA system.

on the system or process using a standardized severity scale. Next, the pre-occurrence of each failure mode is assessed, estimating the likelihood of occurrence before any corrective action is taken, drawing on historical data, expert opinion, or statistical analysis. Subsequently, the capability of existing controls or detection methods to identify and mitigate the effects of each failure mode before significant issues arise is evaluated as part of a pre-detection assessment. The pre-risk priority number (Pre-RPN) is calculated by multiplying pre-severity, pre-occurrence, and pre-detection scores, as in Equation 2, providing a quantitative measure of risk. If the pre-RPN exceeds a predefined threshold, typically set at 100, relevant stakeholders are notified via email, and the Plan phase is initiated for further analysis and improvement efforts. Conversely, if the pre-RPN is below the threshold, the process continues to assess additional failure modes, ensuring comprehensive risk identification and management.

$$\text{Pre-RPN}=\text{Pre-Severity}\times\text{Pre-Occurence}\times \\ \times\text{Pre-Detection} \tag{2}$$

Phase 2: Plan – The focus shifts to proactive measures for addressing identified failure modes. Firstly, a cross-functional team is assembled, leveraging diverse expertise to tackle the identified challenges effectively. Then, SMART goals are established, providing clear direction for improvement efforts. Root cause analysis uses appropriate tools such as Fishbone diagrams or the 5 Whys technique to uncover underlying factors contributing to each failure mode. Subsequently, consensus-building techniques like multi-voting are employed to prioritize and select the primary root cause for each issue. Once root causes are identified, brainstorming sessions are held to generate potential solutions. These solutions are then evaluated using consensus-building techniques to select the most effective option for each root cause.

Lastly, the chosen solutions undergo confirmation to ensure alignment with the established SMART goals, reinforcing the focus on targeted and measurable outcomes throughout the improvement process.

Phase 3: Do – The focus shifts towards action as the chosen solutions to address the identified root causes are implemented. It involves executing the selected strategies while ensuring clear assignment of responsibilities among team members and stakeholders. Continuous progress monitoring is essential to track the effectiveness of the implemented solutions and make adjustments as needed, fostering a dynamic and responsive approach to problem-solving within the organization.

Phase 4: Check Post-RPN – The RPN value is reassessed by considering updated factors such as severity, occurrences, and detection related to the problem, as in Equation 3. Previous PDCA designs a new set of solutions to enhance the RPN by reducing the frequency of occurrences and improving the detection of potential issues. By diminishing these factors, the RPN values can be lowered, thus mitigating the risk of failure. The FMEA table will be updated for future reference as part of this process.

$$\text{Post-RPN}=\text{Post-Severity}\times\text{Post-Occurence}\times \times\text{Post-Detection} \quad (3)$$

Phase 5: Act – The emphasis is on consolidating the outcomes of the FMEA-PDCA process through documentation and knowledge sharing. It involves documenting all findings, actions taken, and outcomes encountered during the process, ensuring comprehensive records for future reference and analysis. Knowledge sharing is integral, as learnings and best practices derived from the FMEA-PDCA process are disseminated among relevant stakeholders. This sharing of insights fosters a culture of continuous improvement and organizational learning, enabling the accumulation of collective wisdom to inform future endeavors and enhance overall organizational effectiveness.

5. Case study

5.1. Company background

The case study takes place in a semiconductor company in Batu Kawan, Penang, Malaysia, called Company XYZ. Since its inception in 2000, Company XYZ has established itself as a prominent player in the technology landscape. This innovative firm specializes in designing and manufacturing automated vision inspection equipment and system-on-chip embedded electronics devices for the semiconductor and electronics packaging industries. With a dedicated workforce and advanced production lines, Company XYZ has garnered a strong reputation for its cutting-edge solutions. Boasting more than 1039 employees, it serves various industries, including semiconductor Outsourced Assembly and Test (OSAT) companies, printed circuit board manufacturers, electronics assembly companies, Original Equipment Manufacturers (OEM), Original Design Manufacturers (ODM), Electronics Manufacturing Services (EMS) providers and Contract Manufacturers (CM) around the world. It is committed to fostering innovation, sustainability, and community engagement.

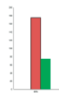
5.2. FMEA-PDCA system implementation

The wiring and assembly process is in assembly line A of Company XYZ.

Pre-RPN in FMEA of the failures in Assembly Line A – During an inspection of the pick and place machine in the Assembly Line A, a recurring issue with screw loosening in the TTM module was detected. If not addressed, this malfunction could lead to instability in the arm responsible for tray pickup, potentially resulting in dropped trays during machine operation and disrupting the tray transfer process. Following this discovery, an FMEA meeting was convened with relevant stakeholders to address the concerns. In this meeting, the severity, occurrence, and detection of the issue were assessed and rated. The resulting RPN value was calculated, with a value of 175 exceeding a set threshold of 100 for Company XYZ. PDCA was deemed necessary to rectify the failure.

PDCA of the failure in Assembly Line A – To address the recurring failure in Assembly Line A, a team comprising a team leader (main author), mentor (Lean Six Sigma Black Belt holder), champion (Manufacturing Manager), and five cross-functional team members, was established to implement PDCA. A SMART goal was set, which is to reduce the occurrence of loose tray screws from 7 to 3 by June 10, 2023. During the Plan phase, a 6M (machine, method, man, measurement, material, mother nature) was utilized to pinpoint potential root causes of screw loosening, as in Figure 3. Three potential root causes were identified under the category of Man (human error), Material (tool malfunction), and Method (wrong tightening method). A multi-voting tool was applied to pinpoint the select critical root cause, and three out of five members voted for material (tool malfunction) as the critical root cause

Pre-RPN in FMEA								
Process	Failure	Potential impact	*SEV*	Potential causes	*OCC*	Current control	*DET*	RPN
Assembly line A	Loose tray screw	The unit might be damaged	5	-No proper position teaching -Tuning personnel do not follow WI -New tuning personnel	7	Provide proper WI for a position teaching	5	175 If more than 100, conduct PDCA

PLAN						DO	CHECK	ACT	
Team members	SMART goal	Root cause analysis – 6M	Multi-voting	Potential Action	Multi-voting	Implement Action	Comparison RPN	Standardize	Yokoten
Team leader: Main author Mentor: Mr. A Champion: Mr. B Team members: Mr. C, Mr. D, Mr. E, Mr. F	To improve *Loose tray screw* from *Occ 7* to *Occ 3* by *10/6/2023.*	Man – *Human error* Material – *Tool malfunction* Method – *Wrong tightening* Measurement – Machine – Mother Nature –	Team leaders and team members vote (3 out 5 votes for tools malfunction)	Tools malfunction: #1. Replace the tools every 2 months #2. Use torque wrench	Team leaders and team members vote (4 out 5 vote #2)	Implement torque wrench in assembly line A on 15/5/2023		Use the same tools	Apply the torque wrench to Assembly line B

Post-RPN in FMEA									
Process	Failure	Potential impact	*New SEV*	Root cause analysis – 6M	*New OCC*	Current control	*New DET*	New RPN	Improvement
Assembly line A	Loose tray screw	The unit might be damaged	5	Man – *Human error* Material – *Tool malfunction* Method – *Wrong tightening* Measurement – Machine – Mother Nature –	3	Use torque wrench	5	75	57.14%

Figure 3. The integration of FMEA and PDCA to address failures within Company XYZ.

of the screw loosening problem. The team suggested two potential actions: replacing tools every two months and applying a torque wrench. Again, multi-voting was used to select the best solution, and four out of five voted for using a torque wrench. Torque wrench provides precise control, ensuring screws are tightened to specifications, preventing damage, and ensuring safety in Assembly Line A. In the Do phase, torque wrenches were introduced to the operators in Assembly Line A to ensure proper screw tightening. During the Check phase, the implementation underwent two weeks of monitoring to verify process stability, and occurrences of screw-loosening failures were tracked. The failure instances were reassessed to update the RPN. Over the two weeks, the failure occurrences decreased to 3, resulting in a new RPN value of 75, marking a 57.14% improvement and meeting the target of an RPN below 100. A bar chart was employed to compare the RPN values before and after the implementation. In the Act phase, the findings were disseminated (Yokoten) to other comparable assembly lines, sharing best practices. Organizations can promote consistency, efficiency, and continuous improvement across various departments or facilities by disseminating these findings.

Post-RPN in FMEA of the failures in Assembly Line A – PDCA in Assembly Line A led to a significant decrease in the occurrence rate of a particular failure, indicated by a reduction in its post-RPN to 75, with a severity of 5, occurrence of 3, and detection of 5. Acknowledging the effectiveness of this strategy, the application of PDCA to other assembly lines has also resulted in favorable outcomes, demonstrating a consistent decrease in RPN values and a notable 57.14% improvement in addressing the targeted failure throughout the manufacturing process. These findings were subsequently documented once more in the FMEA table. These successful outcomes and insights gained from the PDCA implementation were shared with relevant stakeholders across other assembly lines. This knowledge dissemination aimed to facilitate cross-departmental learning and encourage the adoption of effective strategies to address similar challenges in different manufacturing processes.

6. Discussion

The case study underscores the effectiveness of the framework in pinpointing significant production process failures through the utilization of FMEA. Engineers can strategically pinpoint areas for process improvement within PDCA by focusing on high RPN values. The implementation of PDCA led to a noteworthy 57.14% improvement in RPN values, all of which dropped below the critical threshold of 100. This notable enhancement validates the success of the integrated approach in mitigating risks and streamlining processes. When juxtaposed, the traditional employment of FMEA or PDCA alone proves less impactful than the combined utilization of both methodologies. FMEA, being a one-time or periodic endeavor, suggests that without continuous

Table 3. Comparison between traditional FMEA, traditional PDCA, and FMEA-PDCA system.

Aspect	Old FMEA	Old PDCA	FMEA-PDCA system
Nature of Activity	One-time or periodic activity	Continuous improvement cycle	Continuous improvement cycle
Primary Focus	Identifying failure modes	Process improvement	Risk assessment and process improvement
Data Dependency	It highly depends on the data	Data-driven	Data-driven
Reliance on Experience	It highly depends on individual experience	Emphasizes systematic analysis	Emphasizes systematic analysis
Employee Involvement	Limited involvement	Emphasizes involvement	Encourages involvement at various stages
Root Cause Analysis	Limited emphasis	Part of the Plan phase	Part of the Plan phase
Solution Determination	Not included	Part of the Plan phase	Part of the Plan phase
Iterative Process	Not inherently iterative	Inherently iterative	Inherently iterative

PDCA, new risks may arise over time. Within the PDCA, the team delved deeper into the root cause analysis during the Plan phase, using tools like the Fishbone diagram to identify potential factors contributing to the problem. By analyzing aspects of 6M's, the team pinpointed tool malfunction as the critical root cause of screw loosening. This level of detailed analysis allowed them to develop targeted solutions to address the underlying issues rather than merely treating the symptoms.

In the Check and Act phases of PDCA, this case study showcases the capability to delve deeper into failure modes, uncovering root causes to prevent recurrence, especially in the semiconductor industry. Additionally, the absence of FMEA-PDCA integration may lead to data limitations within the PDCA, potentially resulting in inaccuracies in analysis.

This research explains how the FMEA-PDCA system enables organizations to comprehensively identify potential failure modes and associated risks, providing a more thorough understanding of potential vulnerabilities. By combining systematic analysis with the iterative problem-solving approach of FMEA and PDCA, organizations can foster a culture of continuous improvement, allowing for ongoing refinement of risk mitigation strategies based on real-world data and feedback. FMEA-PDCA system facilitates more effective root cause analysis, as teams can systematically analyze failure modes within the PDCA to identify and address underlying causes more accurately, leading to more sustainable solutions and fewer recurring issues. Integrating FMEA with PDCA helps organizations allocate resources more efficiently by prioritizing high-risk areas identified through FMEA within the PDCA cycle. This allows teams to focus their efforts and resources on addressing the most critical issues first. By adopting a standardized approach to risk management and continuous improvement through the FMEA-PDCA system, organizations can promote better alignment and collaboration across different departments and teams, fostering a shared understanding of goals, processes, and best practices.

6.1. Comparison between traditional FMEA, traditional PDCA, and integration FMEA-PDCA

Traditional FMEA is typically a one-time or periodic activity commonly conducted during a project design, product design, or planning phase. It primarily focuses on identifying potential failure modes, their effects, and associated risk levels, relying heavily on data and often on individual experience. In contrast, traditional PDCA represents a continuous improvement cycle, where actions are iteratively planned, executed, checked, and adjusted. Its main objective is to improve existing processes, products, or services, emphasizing systematic analysis, data-driven decision-making, and employee involvement during the improvement process. The FMEA-PDCA system integrates risk assessment in traditional FMEA and process improvement in traditional PDCA into an ongoing, systematic process. This approach ensures a holistic and continuous approach to addressing issues, enhancing processes, and identifying root causes.

Data plays a crucial role in all three approaches, with traditional FMEA relying on data for risk assessment, traditional PDCA analyzing data to evaluate process improvements, and the integrated approach valuing data in risk assessment and process analysis. Employee involvement differs significantly among the approaches. Traditional FMEA generally has limited employee involvement, while traditional PDCA encourages it, particularly during improvement. The integrated approach fosters employee participation at various stages, ensuring a broader perspective on risk assessment and improvement efforts. Root cause analysis is not typically emphasized in traditional FMEA but becomes an integral part of the Plan phase in traditional PDCA. The integrated approach also incorporates root cause analysis during the Plan phase, enhancing problem-solving capabilities. Solution determination is usually not included in the scope of traditional FMEA. However, it is a crucial component of the Plan phase in traditional PDCA. In the integrated approach, solution determination is also part of the Plan phase, ensuring a comprehensive strategy for addressing identified issues or improvements.

Regarding an iterative process, traditional FMEA may not adapt as readily to new data as the other two approaches. While traditional PDCA inherently follows an iterative cycle, it primarily focuses on process improvement rather than risk assessment. The integrated approach combines the iterative nature of PDCA with the risk assessment capabilities of FMEA, providing a comprehensive and adaptive framework for continuous improvement and risk management. Table 3 compares traditional FMEA, traditional PDCA, and integrated FMEA-PDCA systems.

7. Conclusion

This research integrates FMEA and PDCA for risk management and process improvement in the semiconductor industry. The study reveals a significant 57.14% reduction in RPN values, all below the critical threshold of 100, validating the effectiveness of the framework in mitigating risks and enhancing process reliability. The combined use of FMEA and PDCA facilitates thorough root cause analysis and targeted solutions, addressing underlying issues rather than mere symptoms. This iterative approach ensures continuous monitoring and adaptation, which is suitable for the dynamic nature of semiconductor manufacturing. The practical contributions of this research are multifaceted. First, FMEA-PDCA system provides a robust mechanism for identifying and prioritizing potential failure modes, ensuring that high-risk areas are addressed promptly and effectively. Second, by optimizing resource allocation, semiconductor manufacturers can enhance productivity and cost-efficiency, improving overall competitiveness. Third, fostering a culture of continuous improvement through this inclusive methodology promotes better collaboration and alignment across departments, leading to more effective and sustainable solutions. Future research should focus on developing industry-specific guidelines and tools for implementing the FMEA-PDCA system in semiconductor manufacturing. Tailored solutions that address the unique complexities and stringent quality standards of semiconductor processes can further enhance the effectiveness of this integrated approach. The longitudinal studies to monitor the long-term impacts of FMEA-PDCA system on organizational performance and resilience will provide deeper insights. Investigating the potential of incorporating advanced data analytics and machine learning into the FMEA-PDCA framework could also offer innovative ways to predict and mitigate risks more proactively.

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Authors contribution

Hi Ding Hock contributed to the data collection, analysis, and interpretation, while also aiding in drafting and revising the manuscript. Nur Amalina Muhammad played a significant role in analyzing data and contributing to the drafting and revision of the manuscript. Noorhafiza Muhammad provided valuable insights during the data analysis phase and contributed to the drafting and revision process of manuscript.

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