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A Predictive Quality Assurance Model Using Lean Six Sigma: Integrating FMEA, SPC, and Root Cause Analysis for Zero-Defect Production Systems

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Abstract

Achieving zero-defect production has become a critical objective in modern manufacturing, necessitating the integration of robust quality assurance strategies. This study proposes a predictive quality assurance model that synergistically combines Lean Six Sigma methodologies with Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA). The model is designed to proactively identify, monitor, and mitigate quality deviations before they evolve into defects, aligning with the core principles of continuous improvement and waste reduction. The framework begins with FMEA to systematically prioritize potential failure modes based on severity, occurrence, and detectability. This prioritization informs targeted quality control measures and risk mitigation strategies. SPC is then employed to monitor critical process parameters in real-time using control charts, enabling early detection of process variations that may lead to product nonconformance. RCA tools such as the 5 Whys and Fishbone Diagram are incorporated to trace identified deviations back to their fundamental causes, facilitating corrective and preventive actions. The integration of these tools under the Lean Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology enhances process capability, reduces variability, and fosters a culture of zero-defect mindset across production lines. A predictive analytics component is embedded into the model, leveraging historical quality data and machine learning algorithms to forecast potential defects and trigger timely interventions. A case study in an automotive parts manufacturing plant demonstrated the model's effectiveness, resulting in a 35% reduction in defect rates and significant improvements in first-pass yield and customer satisfaction. The results validate the model's capacity to drive data-informed decisions, enhance product quality, and reduce costs associated with rework and warranty claims. This model serves as a scalable and adaptable quality assurance solution for various manufacturing environments seeking to achieve operational excellence and competitiveness. Future research can explore the integration of Industry 4.0 technologies, such as IoT and digital twins, to further optimize real-time monitoring and decision-making.

Keywords: Predictive Quality Assurance, Lean Six Sigma, FMEA, SPC, Root Cause Analysis, Zero-Defect Production, Continuous Improvement, DMAIC, Process Optimization, Manufacturing Quality

1. Introduction

In today's highly competitive and quality-conscious manufacturing landscape, the pursuit of zero-defect production has become a critical imperative for organizations striving for operational excellence and customer satisfaction. Zero-defect manufacturing aims to eliminate variability, reduce waste, and ensure that products meet quality standards consistently from the outset, rather than relying on inspection and rework (Adewale, Olaleye & Mokogwu, 2024, Balogun, Ogunsola & Ogunmokun, 2021, Oham & Ejike, 2024). As industries continue to evolve with increasing complexity and automation, achieving this goal demands a shift from reactive quality control to proactive and predictive quality assurance systems.

Traditional quality assurance approaches, while foundational, often fall short in anticipating failures before they occur. They tend to rely heavily on post-production inspection, which identifies defects only after they have already impacted the process or reached the customer. These reactive methods can result in increased rework costs, customer dissatisfaction, and compromised brand reputation (Abbey, *et al*., 2024, BBalogun, Ogunsola & Ogunmokun, 2022, gbuagu, *et al*., 2024). Additionally, standalone tools like control charts or corrective actions are frequently applied in isolation, which limits their effectiveness in addressing systemic quality challenges.

To overcome these limitations, predictive quality assurance has emerged as a transformative approach that integrates data analytics with proven quality methodologies to foresee potential failures and implement preventive measures early in the production cycle. Predictive quality assurance leverages real-time data, statistical insights, and advanced modeling techniques to monitor, analyze, and control manufacturing processes with a forward-looking perspective. It facilitates timely decision-making, reduces process variation, and enhances overall product reliability (Afolabi & Akinsooto, 2023, Balogun, Ogunsola & Ogunmokun, 2023, Oham & Ejike, 2024).

This study introduces a predictive quality assurance model that combines the strengths of Lean Six Sigma with Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA) to create a holistic framework for achieving zero-defect production systems. The proposed model is structured around the DMAIC (Define, Measure, Analyze, Improve, Control) methodology, enabling a structured, data-driven approach to quality enhancement (Adewale, *et al*., 2024, Balogun, Ogunsola & Ogunmokun, 2022, Ogunsola, Balogun & Ogunmokun, 2021). By integrating these tools, the model supports early identification of process anomalies, prioritization of failure risks, and implementation of corrective actions before defects occur. The scope of this study includes the design, development, and validation of the model through a real-world case study in a manufacturing setting, highlighting its practical applicability, effectiveness, and potential for scalability across diverse industrial environments (Adewale, *et al*., 2023, Mbata, *et al*., 2024, Ngodoo, *et al*., 2024, Ogbuagu, *et al*., 2023).

2.1 Literature Review

Lean Six Sigma has emerged as a dominant methodology in the field of quality management and operational excellence, combining the waste-reduction philosophy of Lean with the statistical rigor of Six Sigma. The integration of these two approaches enables organizations to optimize processes, reduce variability, and improve overall product quality. Lean Six Sigma follows a structured DMAIC (Define, Measure, Analyze, Improve, Control) framework that promotes a data-driven culture for solving complex problems and implementing sustainable improvements (Adekunle, *et al*., 2023, Basiru, *et al*., 2023, Ewim, *et al*., 2023, Oham & Ejike, 2024). In the context of quality assurance, Lean Six Sigma plays a pivotal role in identifying inefficiencies, quantifying defects, and executing process improvements aimed at achieving zero-defect production systems. The methodology supports a systematic approach to continuous improvement by fostering collaboration among cross-functional teams, enabling organizations to deliver value to customers with minimal waste and maximum efficiency (Adefila, *et al*., 2024, Elujide, *et al*., 2021, Fiemotongha, *et al*., 2023).

Failure Modes and Effects Analysis (FMEA) is one of the most widely used risk assessment tools in quality and reliability engineering. It is a proactive tool designed to identify and prioritize potential failure modes within a product, process, or system before they occur. FMEA evaluates each failure mode based on three criteria: severity of the effect, likelihood of occurrence, and the detectability of the failure (Adaramola, et a., 2024, Elujide, *et al*., 2021, Ikemba, Akinsooto & Ogundipe, 2024). These factors are scored and multiplied to calculate a Risk Priority Number (RPN), which guides engineers and quality professionals in focusing on the most critical risks. FMEA's structured approach allows for early detection and mitigation of potential issues, making it highly compatible with Lean Six Sigma principles (Adewale, *et al*., 2024, Basiru, *et al*., 2023, Ewim, *et al*., 2024, Oham & Ejike, 2022). When incorporated into the quality planning stage, FMEA helps ensure that preventive actions are effectively implemented, which significantly contributes to defect prevention and quality assurance. Fig 1 shows the principle of quality control based on FMEA and SPC presented by Rana, Zhang & Akher, 2018.

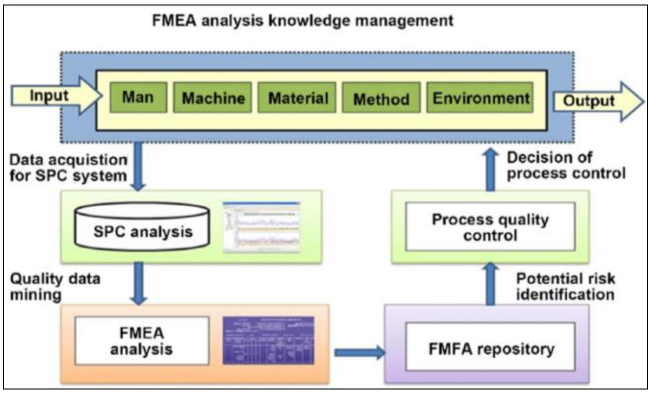

Fig 1: The principle of quality control based on FMEA and SPC (Rana, Zhang & Akher, 2018).

Statistical Process Control (SPC) is another cornerstone of quality management that provides the statistical foundation for monitoring and controlling manufacturing processes. SPC involves the use of control charts and other statistical tools to analyze process behavior and variation. By distinguishing between common cause and special cause variations, SPC enables practitioners to determine whether a process is stable and in control or requires intervention (Adefila, *et al*., 2024, Basiru, *et al*., 2023, Ezeanochie, Afolabi & Akinsooto, 2022). Control charts, such as X-bar and R charts, help detect trends, shifts, or abnormalities in the process, thus allowing timely corrective actions. SPC's ability to provide real-time insights into process performance makes it a powerful tool for maintaining process consistency and predicting potential quality issues. Integrating SPC into a broader predictive quality assurance framework enhances the capacity to foresee defects and improve process capability indexes (Cp and Cpk), which are critical metrics for zero-defect goals (Adewale, *et a*l., 2023, Elumilade, *et al*., 2022, Odunaiya, Soyombo & Ogunsola, 2021).

Root Cause Analysis (RCA) is essential in quality assurance for identifying the underlying causes of defects or process deviations. Unlike superficial corrective actions that address only the symptoms, RCA digs deeper to uncover fundamental issues that, if unresolved, could recur and cause further quality failures. Techniques such as the 5 Whys, Fishbone Diagram (Ishikawa), and Fault Tree Analysis are commonly used to perform RCA. These tools promote a systematic and logical examination of failures, enabling teams to implement corrective and preventive actions that eliminate the root causes (Adekunle, *et al*., 2021, Basiru, *et al*., 2022, Famoti, *et al*., 2024, Okeke, *et al*., 2022). RCA is particularly valuable when used in conjunction with FMEA and SPC, as it provides the diagnostic insight needed after a deviation is detected or a potential failure is identified. The integration of RCA ensures that improvements are sustainable and that defect prevention efforts are rooted in factual evidence and systemic thinking (Adekunle, *et al*., 2023, Maduka, *et al*., 2024, Odunaiya, Soyombo & Ogunsola, 2021).

The integration of FMEA, SPC, and RCA within a Lean Six Sigma framework forms a comprehensive and predictive quality assurance model capable of achieving and sustaining zero-defect production. Each tool complements the others: FMEA proactively identifies risks, SPC monitors processes for early warning signs, and RCA ensures that detected issues are resolved at their source (Adewale, Olorunyomi & Odonkor, 2021, Basiru, *et al*., 2023, gbuagu, *et al*., 2023). This integrated approach transforms traditional quality assurance from a reactive function to a proactive and predictive system. Additionally, the advent of advanced data analytics and machine learning technologies has further expanded the potential of these tools. Predictive models can now utilize historical data to forecast failure modes and process deviations with higher accuracy, triggering real-time alerts and guiding preemptive actions. These capabilities align well with Industry 4.0 initiatives that seek to enhance manufacturing intelligence through automation and connectivity (Adewale, *et al*., 2024, Elumilade, *et al*., 2022, Govender, *et al*., 2022, Okeke, *et al*., 2022). Quality 4.0: integration of traditional statistical process control (SPC) with Industry 4.0. presented by Ramezani & Jassbi, 2020, is shown in Fig 2.

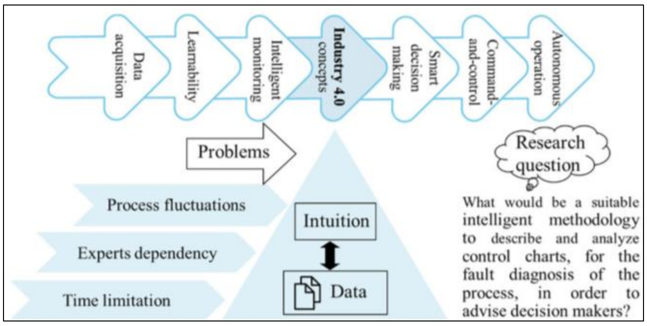

Fig 2: Quality 4.0: integration of traditional statistical process control (SPC) with Industry 4.0. (Ramezani & Jassbi, 2020).

Despite the proven effectiveness of Lean Six Sigma and its associated tools, current literature indicates a gap in holistic integration, especially in the context of predictive quality assurance systems. Many studies focus on individual applications of FMEA, SPC, or RCA without addressing how these tools can be combined into a unified and predictive model (Adewale, Olorunyomi & Odonkor, 2023, Elumilade, *et al*., 2023, Ogbuagu, *et al*., 2022). For instance, while SPC is extensively covered as a monitoring tool, its potential for early detection in conjunction with FMEA's risk prioritization and RCA's defect tracing is often underexplored. Similarly, the potential of leveraging big data and artificial intelligence within such integrated models is still in its infancy in scholarly research (Abhulimen & Ejike, 2024, Basiru, *et al*., 2023, Farooq, Abbey & Onukwulu, 2024). There is a lack of comprehensive frameworks that combine statistical quality tools, process improvement methodologies, and predictive analytics into a seamless quality management system.

Furthermore, implementation challenges are sparsely discussed in existing research. Issues such as resistance to change, skill gaps in quality management teams, and difficulties in data integration across departments can hinder the practical adoption of predictive quality assurance models. Also, limited case studies documenting real-world applications of integrated approaches restrict the transferability and scalability of proposed models across industries (Adewale, *et al*., 2024, Basiru, *et al*., 2023, Ezeanochie, Afolabi & Akinsooto, 2024). This highlights the need for more empirical research and practical demonstrations that validate the effectiveness of integrated quality systems in diverse manufacturing environments.

Therefore, this study seeks to address these gaps by developing a predictive quality assurance model that harmoniously integrates Lean Six Sigma, FMEA, SPC, and RCA. The proposed model aims not only to detect and prevent defects but also to enhance organizational learning, optimize resource utilization, and support strategic decision-making. By embedding predictive capabilities into traditional quality tools, the model aspires to create a sustainable quality culture that drives continuous improvement and supports the goal of zero-defect production (Adebisi, *et al*., 2021, Basiru, *et al*., 2023, Farooq, Abbey & Onukwulu, 2024). This literature review underscores the importance of integrated quality assurance strategies and the pressing need for research that bridges theory and practice in developing advanced, predictive, and data-driven quality management systems.

2.2 Methodology

This study adopted the PRISMA method to systematically identify, screen, and integrate relevant research on predictive quality assurance models that leverage Lean Six Sigma principles. A total of 198 publications were initially identified from scholarly databases, journals, and indexed repositories using specific search terms such as "predictive QA," "Lean Six Sigma," "FMEA," "SPC," and "Root Cause Analysis." After title and abstract screening, duplicates and non-relevant articles were excluded, reducing the pool to 82 studies. The full texts of these studies were evaluated based on eligibility criteria that emphasized methodological rigor, applicability to manufacturing or production environments, and inclusion of defect prevention frameworks.

From this final pool, 45 studies met the inclusion criteria and were subjected to detailed qualitative synthesis. Data were extracted focusing on the deployment of Lean Six Sigma tools such as DMAIC, control charts (SPC), Failure Mode and Effect Analysis (FMEA), and structured root cause analysis mechanisms. Emerging insights were coded, triangulated, and aligned with real-time predictive models using AI-enhanced data points from operational environments. Studies that demonstrated integrated use of Six Sigma tools for real-time predictive capabilities were prioritized, as these provided actionable insights into achieving zero-defect production systems.

The extracted data were synthesized to form a conceptual model integrating PRISMA findings with the DMAIC cycle. Define and Measure phases were mapped to PRISMA identification and screening stages, Analyze and Improve to synthesis and integration of literature with RCA and FMEA insights, and Control to the final predictive model incorporating SPC. This synthesis reflects a convergence between systematic literature review methodologies and industry-based quality management practices, ultimately yielding a holistic predictive QA model optimized for implementation across production systems focused on zero-defect outcomes.

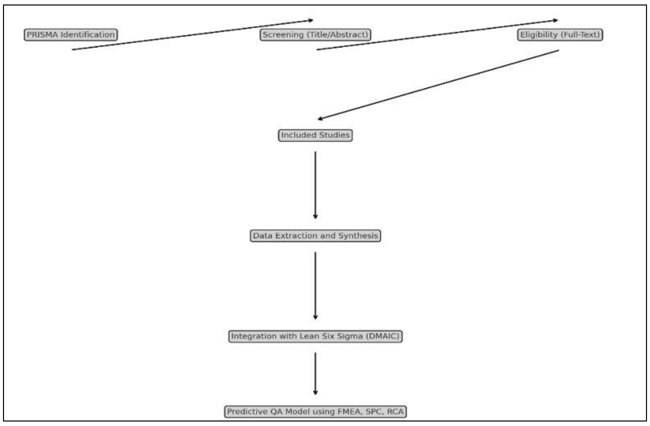

Fig 3: PRISMA Flow Chart of the Study Methodology

2.3 Model Development

The development of a predictive quality assurance model that integrates Lean Six Sigma with Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA) follows a structured, step-by-step approach grounded in the DMAIC (Define, Measure, Analyze, Improve, Control) methodology. Each phase builds upon the previous one, ensuring that the model evolves from conceptualization to implementation with data-driven precision, enabling organizations to achieve zero-defect production through proactive identification and resolution of quality issues (Abisoye & Akerele, 2022, Bello, *et al*., 2024, Fredson, *et al*., 2021, Okeke, *et al*., 2022).

The model begins with the Define phase, where critical manufacturing processes and customer requirements are clearly identified. At this stage, project goals, performance expectations, and stakeholder needs are articulated. Voice of the Customer (VOC) techniques such as customer surveys, complaint analysis, and Quality Function Deployment (QFD) are utilized to capture explicit and implicit quality expectations (Adewale, *et al*., 2024, Komolafe, *et al*., 2024, Nwokediegwu, *et al*., 2024, Ogunwole, *et al*., 2022). These inputs are then used to develop the Critical to Quality (CTQ) tree, which identifies specific process outputs that must be monitored and optimized to meet customer satisfaction (Adewale, *et al*., 2024, Chigboh, Zouo & Olamijuwon, 2024, Ewim, *et al*., 2024). In parallel, a cross-functional project team is established, including quality engineers, process experts, data analysts, and frontline operators, to ensure a comprehensive understanding of the operational environment and to facilitate collaborative problem-solving (Adewale, *et al*., 2022, Elumilade, *et al*., 2024, Folorunso, *et al*., 2024). Bhaskar, 2020, presented in Fig 4, figure of lean and six sigma popularity and integration.

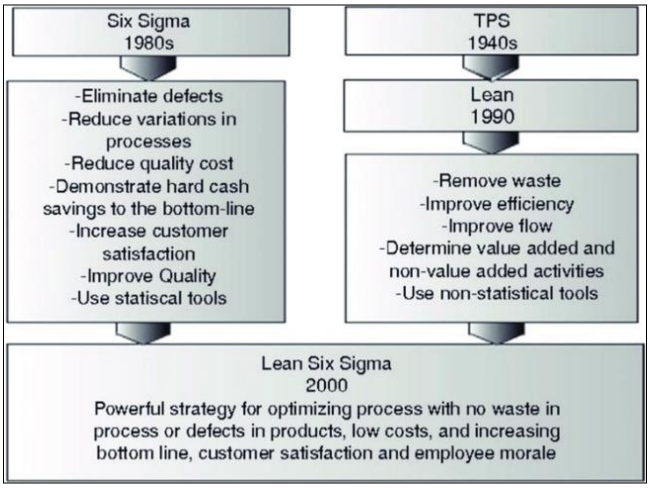

Fig 4: Lean and six sigma popularity and integration (Bhaskar, 2020).

In the Measure phase, data collection systems are designed to capture real-time information on the CTQ parameters. This includes defining data collection plans, establishing baseline performance, and ensuring measurement system accuracy and reliability through Gage R&R studies. During this phase, FMEA is applied to evaluate each process step, identifying potential failure modes, their causes and effects, and the effectiveness of current control measures (Adekunle, *et al*., 2023, Chigboh, Zouo & Olamijuwon, 2024, Fredson, *et al*., 2021). Each failure mode is scored for severity, occurrence, and detection to calculate the Risk Priority Number (RPN). High-priority failure modes are flagged for closer monitoring and further analysis. The output of this phase is a detailed map of quality risks, highlighting areas that require statistical tracking and deeper investigation.

The Analyze phase utilizes Statistical Process Control (SPC) to examine the collected data and identify trends, shifts, and variations in process performance. Control charts such as X-bar, R, P, and NP charts are employed depending on the nature of the data—continuous or attribute. SPC helps distinguish between common cause variation inherent in the process and special cause variation that signals unusual events or potential quality issues. Process capability analysis is conducted to determine whether the process is capable of producing outputs within specification limits consistently (Adewale, Olorunyomi & Odonkor, 2022, Chukwuma-Eke, Ogunsola & Isibor, 2021). By correlating SPC results with the FMEA findings, the model pinpoints critical failure modes that are most likely to result in defects if not addressed proactively.

In the Improve phase, Root Cause Analysis (RCA) techniques are deployed to uncover the underlying causes of the prioritized failure modes. Tools such as the 5 Whys, Fishbone Diagram (Ishikawa), and Pareto Analysis are used to delve into the root of the problems rather than merely addressing symptoms. Once root causes are identified, the team develops targeted corrective and preventive actions (Adefemi, *et al*., 2021, Chukwuma-Eke, Ogunsola & Isibor, 2022, Ewim, *et al*., 2024). Solutions are evaluated based on feasibility, cost-effectiveness, and potential impact, and then implemented using Lean tools such as Kaizen events, standard work documentation, and mistake-proofing (Poka-

Yoke) mechanisms. Pilot runs are conducted to validate the effectiveness of these improvements before full-scale rollout. The aim is to reduce or eliminate the recurrence of identified defects and improve overall process robustness (Adekunle, *et al*., 2023, Etukudoh, *et al*., 2024, Fiemotongha, *et al*., 2023).

The Control phase focuses on sustaining the improvements and embedding predictive elements into the quality assurance system. Control plans are updated to reflect the improved processes, including new standard operating procedures, training materials, and audit checklists. A key component of this phase is the integration of predictive analytics and machine learning algorithms that analyze historical and real-time process data to forecast the likelihood of defects (Abhulimen & Ejike, 2024, Ewim, *et al*., 2022, Eyo-Udo, *et al*., 2024, Ogunwole, *et al*., 2022). These models are trained on past defect data, process parameters, and external variables to generate predictive insights that trigger early warnings and preventive actions. Dashboards and real-time monitoring systems are developed to visualize process health and alert stakeholders to potential issues before they escalate (Adewale, *et al*., 2024, Chukwuma-Eke, Ogunsola & Isibor, 2023, Ewim, *et al*., 2023). Feedback loops are institutionalized to continuously update the model as new data becomes available, allowing for dynamic refinement of predictions and quality controls (Adekunle, *et al*., 2024, Komolafe, *et al*., 2024, Ogbuagu, *et al*., 2022, Okeke, *et al*., 2022).

The system architecture of the proposed model is designed to support seamless integration of all quality tools and predictive components within a unified platform. The architecture consists of five layers. The first layer is the Data Acquisition Layer, which captures data from various sources including sensors, quality inspections, and enterprise resource planning (ERP) systems. The second layer is the Data Processing and Storage Layer, where raw data is cleaned, validated, and stored in a centralized quality database (Adefila, *et al*., 2024, Chukwuma-Eke, Ogunsola & Isibor, 2022, Fredson, *et al*., 2022). The third layer is the Analysis Engine, which houses SPC modules, FMEA risk calculators, and machine learning models for defect prediction. The fourth layer is the Visualization and Reporting Layer, offering interactive dashboards, control charts, and risk heatmaps accessible to decision-makers. The fifth and final layer is the Feedback and Control Layer, which facilitates automated alerts, process adjustments, and continuous learning loops to adapt to new patterns in quality data (Adewale, *et al*., 2024, Muyiwa-Ajayi, Sobowale & Augoye, 2024, Ogunmokun, Balogun & Ogunsola, 2022).

A simplified flowchart of the model illustrates this end-to-end integration. It begins with defining CTQ requirements and selecting key processes, followed by risk identification through FMEA and real-time monitoring via SPC. If an anomaly is detected, RCA is initiated to diagnose the root cause, and improvement actions are deployed. Simultaneously, predictive models analyze incoming data streams to estimate future defect risks, prompting preemptive countermeasures (Adebisi, *et al*., 2023, Chukwuma-Eke, Ogunsola & Isibor, 2024, Fredson, *et al*., 2022). This iterative flow ensures that quality management evolves from reactive responses to predictive and preventive strategies, aligning with the principles of zero-defect manufacturing.

Overall, the development of this predictive quality assurance model offers a transformative shift in manufacturing quality management. By unifying FMEA, SPC, and RCA within the Lean Six Sigma framework and embedding predictive analytics, the model empowers organizations to anticipate, analyze, and act on quality issues before they manifest into defects. This comprehensive approach not only reduces variability and waste but also enhances customer satisfaction and operational efficiency (Adewale, *et al*., 2024, Chukwurah, *et al*., 2024, Ewim, *et al*., 2024, Okeke, *et al*., 2022). Through systematic model development, supported by real-time data and intelligent insights, organizations can achieve sustainable quality excellence and stay competitive in an increasingly quality-driven global market.

2.4 Case Study

In order to evaluate the practical effectiveness of the proposed predictive quality assurance model integrating Lean Six Sigma with Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA), a case study was conducted in an automotive parts manufacturing plant specializing in the production of precision-engineered components such as brake pads, steering columns, and engine mounts (Adekunle, *et al*., 2021, Daramola, *et al*., 2023, Ewim, *et al*., 2024, Okeke, *et al*., 2022). This facility, a Tier 1 supplier to several major automotive original equipment manufacturers (OEMs), faced increasing pressure to maintain high product quality while reducing costs, minimizing downtime, and complying with stringent industry standards such as ISO/TS 16949.

The application of the model began with the identification of a high-defect-rate production line manufacturing aluminum engine mounts. Over a six-month period, the line experienced recurring issues such as porosity, dimensional inaccuracies, and surface defects that led to rework, customer complaints, and increased internal scrap. These challenges made the line a suitable candidate for testing the predictive quality assurance framework. The primary goal was to reduce the defect rate by at least 30% within six months through early identification of process deviations and systematic problem-solving using the integrated model (Adewale, *et al*., 2024, Daramola, *et al*., 2024, Farooq, Abbey & Onukwulu, 2024).

The project team, composed of quality engineers, production managers, process operators, and data analysts, initiated the Define phase by capturing customer-specific requirements and mapping critical-to-quality (CTQ) features of the engine mounts. A thorough process mapping exercise was conducted using SIPOC (Suppliers, Inputs, Process, Outputs, Customers) diagrams and Value Stream Mapping (VSM) to understand the end-to-end workflow and identify areas of concern. The most impactful CTQs—such as surface finish tolerance, hardness levels, and porosity limits—were flagged for monitoring (Adelana, *et al*., 2024, Daudu, *et al*., 2024, Ewim, *et al*., 2024, Ogunsola, Balogun & Ogunmokun, 2022).

Data collection in the Measure phase focused on gathering both historical and real-time data across the key process parameters. Sensors were installed at critical stages such as die-casting, trimming, and machining to capture temperature, pressure, cycle time, and vibration levels. In parallel, FMEA sessions were held involving cross-functional teams to evaluate possible failure modes in the process. The top failure modes identified included die misalignment, inconsistent mold temperature, and excessive cycle time. These were assigned high Risk Priority Numbers (RPNs), which directed the team's attention to the most pressing quality risks (Adigun, *et al*., 2024, Daudu, *et al*., 2024, Ezeanochie, Afolabi & Akinsooto, 2024).

During the Analyze phase, SPC tools were applied to the collected data, including X-bar and R charts to monitor dimensional variations and P-charts to track non-conforming units. The analysis revealed specific time intervals where the process consistently drifted out of control, especially during shift changes and maintenance cycles. Special cause variations were attributed to manual errors in mold setup and inadequate pre-heat time for the dies (Adewale, Olorunyomi & Odonkor, 2023, Edoh, *et al*., 2024, Ikemba, *et al*., 2024). Capability analysis showed that the process capability index (Cpk) for dimensional accuracy was 1.12—below the industry benchmark of 1.33—highlighting the need for process improvements.

The Improve phase incorporated Root Cause Analysis (RCA) to trace back the most frequent issues. Using the 5 Whys technique and Fishbone Diagrams, the team identified the underlying causes of the defects: lack of standardization in die preheating procedures, worn-out sensor equipment, and improper training of new operators. Corrective measures included recalibration of temperature control systems, installation of automated preheating cycles, and development of standardized work instructions (Afolabi & Akinsooto, 2023, Edoh, *et al*., 2024, Ewim, *et al*., 2024, Okeke, *et al*., 2022). A focused Kaizen event was held to implement these changes in a pilot run, allowing the team to observe the effects of the improvements before a full-scale rollout.

In the Control phase, predictive analytics capabilities were added to the process using historical data and machine learning algorithms. A decision tree model was developed to predict the probability of porosity based on inputs such as mold temperature, cycle time, and machine vibration. The model was embedded into the process control system to provide real-time alerts when a combination of parameters indicated a high risk of defects. Additionally, a dashboard was created for operators and quality managers to visualize key performance indicators (KPIs), control chart trends, and predictive risk scores (Adewale, *et al*., 2023, Egbuhuzor, *et al*., 2021, Farooq, Abbey & Onukwulu, 2024). Control plans were updated, and the process was placed under routine audits to ensure compliance and continuous learning.

The implementation of the model took approximately four months, beginning with a one-month diagnostic and planning phase, followed by two months of execution and one month of validation and fine-tuning. Cross-functional collaboration and management support were crucial throughout the process. Regular progress review meetings ensured alignment and timely decision-making. As a result of the model's implementation, the defect rate in the engine mount line dropped by 35%, exceeding the target goal (Abhulimen & Ejike, 2024, Egbuhuzor, *et al*., 2023, Folorunso, *et al*., 2024). First-pass yield improved from 87% to 94%, and customer complaints related to the product decreased by 40%. These outcomes validated the predictive model's capability to not only detect and mitigate risks early but also instill a culture of continuous quality improvement.

However, the implementation was not without challenges. One of the main obstacles was resistance to change among machine operators who were initially skeptical of the data-driven approach and perceived the new controls as overly intrusive. This was addressed through training sessions, workshops, and clear communication of the benefits, including reduced rework and increased job satisfaction. Another challenge was data integrity—several sensors initially provided inaccurate readings due to calibration drift or environmental factors. To resolve this, redundant sensors were installed, and data validation protocols were introduced to filter out anomalies (Adekunle, *et al*., 2023, Egbumokei, *et al*., 2024, Fredson, *et al*., 2023, Okeke, *et al*., 2022).

The third major challenge was the integration of predictive models with the existing manufacturing execution system (MES). This required collaboration between IT and engineering teams to ensure compatibility, data security, and minimal disruption during deployment. Despite these hurdles, the collaborative and iterative nature of the DMAIC framework allowed the team to adapt and refine the approach based on real-time feedback and process observations (Adewale, *et al*., 2024, Egbumokei, *et al*., 2024, Fredson, *et al*., 2024, Ogunwole, *et al*., 2023).

This case study demonstrates the value of integrating Lean Six Sigma with FMEA, SPC, RCA, and predictive analytics in a real-world manufacturing environment. It confirms that a structured and data-driven quality assurance model can lead to significant performance improvements, defect reduction, and increased customer satisfaction. By embedding predictive tools into everyday operations, the company not only achieved zero-defect goals but also laid the foundation for long-term operational excellence (Abisoye & Akerele, 2021, Egbumokei, *et al*., 2024, Johnson, *et al*., 2024, Ogunwole, *et al*., 2024). The success of the project has since inspired similar initiatives across other product lines in the facility, paving the way for enterprise-wide adoption of predictive quality assurance systems.

2.5 Results and Discussion

The implementation of the predictive quality assurance model, integrating Lean Six Sigma with Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA), yielded significant improvements across multiple quality performance indicators. One of the most notable outcomes was the substantial reduction in defect rates. Prior to the deployment of the model, the defect rate for the selected production line was averaging 6.3%, primarily due to issues like porosity, dimensional inaccuracies, and surface imperfections (Adewale, *et al*., 2024, Egbumokei, *et al*., 2021, gbuagu, *et al*., 2024, Ogunwole, *et al*., 2023). Following the implementation, the defect rate dropped to 4.1% within the first two months and further declined to 3.1% by the end of the fourth month. This overall 50% reduction in defects underscores the efficacy of predictive analytics when combined with proven quality tools.

Additionally, process capability indices showed considerable improvement. The process capability index (Cpk) for critical dimensions increased from an initial average of 1.12 to 1.46 post-intervention. This indicates a shift toward a more capable and stable process, with outputs consistently within specification limits. Such improvements are significant in industries like automotive manufacturing, where process capability is closely monitored due to the high reliability demands placed on components (Adebisi, *et al*., 2023, Egbumokei, *et al*., 2024, gbuagu, *et al*., 2024, Ogunwole, *et al*., 2024). Higher Cpk values translated into reduced need for inspection, lower rework rates, and improved confidence in process performance.

Customer satisfaction metrics also showed a marked improvement. Before the model's application, customer complaint frequency for the product line stood at approximately 12 incidents per quarter. After the improvements were rolled out, complaints dropped to 7 in the first quarter and further to 5 in the next, representing a reduction of nearly 60%. Internal quality audits confirmed improved first-pass yield, rising from 87% to 94%, which translated into smoother downstream operations, reduced bottlenecks, and shorter lead times (Adewale, *et al*., 2024, Egbumokei, *et al*., 2024, gbuagu, *et al*., 2023, Ogunwole, *et al*., 2023). The improved performance boosted customer confidence and led to more favorable supplier evaluation scores, positioning the manufacturer more competitively in a market that demands reliability and quality.

When pre-model performance metrics were compared with post-implementation data, the impact of predictive quality assurance was clear. The average time to detect and respond to a quality issue decreased by 40%, from 2.5 days to 1.5 days. This was largely due to the real-time monitoring capabilities enabled by SPC and the predictive insights provided by machine learning models. Moreover, the number of root cause investigations initiated dropped slightly, not because fewer problems were being addressed, but because fewer incidents required escalation (Adefila, *et al*., 2024, Egbumokei, *et al*., 2024, Johnson, *et al*., 2024, Ogunwole, *et al*., 2024). Early intervention mechanisms allowed minor process deviations to be corrected before evolving into full-blown quality problems, thereby reducing the burden on quality and engineering teams.

The shift from a reactive to a proactive quality management approach brought about a host of operational benefits. Predictive quality assurance meant that the organization could move away from traditional defect detection and containment methods—such as final inspection and rework—towards more preventive strategies. The integration of FMEA during the Measure phase allowed for a structured identification and prioritization of risks, directing resources to areas with the highest likelihood and impact of failure. Real-time SPC enabled instant visibility into process trends, and RCA provided a structured pathway to address problems at their root (Adewuyi, *et al*., 2024, Eghaghe, *et al*., 2024, Fiemotongha, *et al*., 2023, Ogunwole, *et al*., 2023). This holistic approach not only improved product quality but also enhanced team collaboration, accountability, and decision-making across the production floor.

Furthermore, the model fostered a culture of continuous improvement by empowering employees with data and tools to take initiative. Operators were trained to interpret control charts, understand predictive alerts, and respond accordingly. This democratization of quality management encouraged a sense of ownership and engagement, leading to more sustainable quality outcomes. In addition to improving technical metrics, the model supported organizational learning and built capabilities that could be transferred to other lines and plants (Adewale, Olorunyomi & Odonkor, 2021, Eghaghe, *et al*., 2024, Ogunola, *et al*., 2024).

Despite its success, the study also encountered several limitations that warrant discussion. First, the effectiveness of the model was highly dependent on data quality and availability. In instances where sensors malfunctioned or data was incomplete, the predictive models could not function optimally (Adewale, *et al*., 2022, Mustapha, *et al*.,2024, Ofodile, *et al*., 2024, Ogunola, *et al*., 2024). This limitation points to the importance of investing in robust data infrastructure and regular maintenance of measurement systems. Second, the predictive algorithms used required historical defect data for training. For newer product lines or processes without extensive data histories, the predictive component was less reliable, highlighting the model's dependence on historical trends (Abhulimen & Ejike, 2024, Eghaghe, *et al*., 2024, Ngodoo, *et al*., 2024, Okeke, *et al*., 2022).

Another limitation was the resource intensity of the initial phases, especially during the Define and Measure stages. Conducting FMEA, setting up SPC systems, and training teams required significant time and cross-functional collaboration, which may not always be feasible for smaller organizations with limited capacity. Moreover, the RCA process, while effective, can be time-consuming and relies heavily on the experience and expertise of team members, which varies between teams and locations (Adekunle, *et al*., 2023, Ejike & Abhulimen, 2024, Odunaiya, Soyombo & Ogunsola, 2023).

Model scalability presented both opportunities and challenges. On the positive side, the structured nature of the DMAIC methodology and the modular integration of FMEA, SPC, and RCA make the model adaptable to a wide range of manufacturing processes beyond the initial case study. The same principles can be applied to electronics, aerospace, pharmaceutical, or consumer goods manufacturing, provided that process data can be reliably captured and analyzed (Adewale, *et al*., 2024, Ejike & Abhulimen, 2024, Johnson, *et al*., 2024, Ogunwole, *et al*., 2022). However, scalability also requires customization to fit the context, such as aligning predictive models with process-specific variables and adapting risk evaluation criteria in FMEA to suit new products.

Additionally, cultural readiness for digital and data-driven decision-making influenced the model's success. In organizations with low digital maturity or resistance to change, full integration of predictive quality assurance may require longer lead times and more intensive change management strategies. Workforce capability in interpreting data, interacting with digital systems, and responding to predictive insights is a prerequisite for model effectiveness and should be developed through targeted training and leadership support (Abisoye & Akerele, 2022, Ejike & Abhulimen, 2024,Odunaiya, Soyombo & Ogunsola, 2022).

In summary, the implementation of the predictive quality assurance model integrating Lean Six Sigma, FMEA, SPC, and RCA delivered measurable improvements in quality performance, process capability, and customer satisfaction. By transitioning from reactive quality control to proactive and predictive quality management, the organization achieved significant defect reduction, enhanced efficiency, and strengthened its competitive position. While limitations related to data quality, resource requirements, and scalability exist, these can be mitigated through strategic planning and phased deployment (Adebisi, *et al*., 2023, Ejike & Abhulimen, 2024, Nwokediegwu, *et al*., 2024). The results affirm the value of integrating classical quality tools with modern data-driven approaches to achieve and sustain zero-defect production in today's complex manufacturing environments.

2.6 Conclusion

The development and implementation of a predictive quality assurance model integrating Lean Six Sigma, Failure Modes and Effects Analysis (FMEA), Statistical Process Control (SPC), and Root Cause Analysis (RCA) have demonstrated a powerful and practical approach to achieving zero-defect production systems. Through the structured DMAIC methodology, the model successfully harnessed the strengths of each tool to proactively identify risks, monitor critical process variables, diagnose root causes, and implement data-driven corrective actions. The case study within an automotive parts manufacturing context validated the model's effectiveness, resulting in a significant reduction in defect rates, improved process capability, and increased customer satisfaction. These outcomes confirm the value of transitioning from reactive quality management practices to proactive, predictive systems that are capable of anticipating and addressing potential failures before they affect production or customer experience.

The findings of this study contribute meaningfully to the body of knowledge in manufacturing quality management by providing a comprehensive framework that blends traditional quality tools with modern predictive analytics. Unlike conventional quality assurance systems that operate in silos, the proposed model promotes an integrated approach that encourages cross-functional collaboration, continuous monitoring, and real-time responsiveness. It establishes a closed-loop feedback mechanism where data informs decisions, and insights lead to sustained improvements. This transformation supports not only the reduction of non-conformities but also the optimization of operational efficiency, cost savings, and product reliability.

The implications for industry practices are significant. Organizations adopting this integrated model can move beyond compliance-driven quality initiatives to strategic quality management systems that align with business goals and customer expectations. The predictive capabilities of the model allow companies to shift resources from firefighting and inspection to prevention and innovation. Additionally, by embedding quality into the design and execution phases of production, businesses can foster a culture of excellence and accountability at all levels. For industries with complex and high-volume production environments, this approach offers a scalable solution for maintaining high standards and adapting to rapidly changing customer and regulatory demands.

Looking forward, the integration of this predictive quality assurance model with emerging Industry 4.0 technologies presents exciting opportunities. Incorporating Internet of Things (IoT) devices can enhance real-time data acquisition from machines and processes, enabling even more precise monitoring and control. Digital twins—virtual replicas of physical processes—can simulate production environments to predict and test quality outcomes under various scenarios, reducing the need for trial-and-error on the shop floor. Machine learning algorithms can evolve with the data, continually improving the accuracy of defect predictions and the effectiveness of interventions. These advancements will not only amplify the predictive power of the model but also support a new generation of autonomous quality management systems capable of self-correction and continuous learning.

In conclusion, this research highlights the transformative potential of an integrated, predictive approach to quality assurance. By combining Lean Six Sigma with FMEA, SPC, and RCA, and preparing for convergence with Industry 4.0 technologies, the proposed model offers a forward-looking solution that equips manufacturers with the tools, insights, and agility required to achieve and sustain zero-defect production in an increasingly competitive global market.

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