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An Integrated Lean–QMS–SPC Analytical Framework for Process Stability and Sustainable Manufacturing

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Abstract

This study addresses the growing need to integrate operational excellence with sustainability objectives in manufacturing systems. Despite extensive research on Lean Management and Quality Management Systems (QMSs), their combined impact on process performance and resource efficiency remains insufficiently explored, particularly in real industrial contexts. The aim of this study is to develop and apply an integrated Lean–QMS–SPC analytical framework linking process performance improvement with sustainability-related outcomes. A case study was conducted in a high-volume manufacturing environment. The study combined process analysis, system-level assessment, and root cause identification to support targeted improvement actions. The results indicate that the implementation of Lean-oriented practices and supporting methods was associated with improved process stability, reduced variability, and decreased occurrence of nonconformities. These improvements translate into enhanced operational performance and reduced resource consumption associated with rework and defects. A scenario-based estimation model, based on observed defect reduction, is used to assess the potential impact on energy consumption and CO_2 emissions. The study contributes to the literature by operationally integrating SPC analysis, QMS assessment, root cause analysis, and Lean-oriented improvement activities within an industrial manufacturing context. The findings highlight that quality-driven process improvements may support operational efficiency while contributing to resource-efficiency performance.

Keywords: lean management; quality management system (QMS); statistical process control (SPC); process capability; defect reduction; energy efficiency; sustainable manufacturing; CO_2 emissions; industrial energy consumption; process optimization

1. Introduction

Manufacturing systems are responsible for a significant share of global energy consumption and environmental impact, accounting for approximately one-third of total energy use and a substantial portion of industrial CO_2 emissions. According to international energy reports, the industrial sector accounts for approximately 30–40% of global energy consumption and a comparable share of CO_2 emissions. In high-volume production environments, even small inefficiencies in process performance can translate into considerable resource losses and environmental burden. This creates a growing need to integrate operational excellence with sustainability-oriented management approaches.

Supply chain volatility and the transition toward electrification demand stringent dimensional tolerances within contemporary automotive structural component manufacturing [1–3]. Organizations are therefore required to continuously improve operational

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performance while simultaneously addressing growing sustainability expectations, including material and energy performance, waste reduction, and environmental impact mitigation [4–7]. These challenges are particularly relevant in the context of energy-intensive manufacturing systems, where process inefficiencies directly translate into increased energy consumption and environmental impact.

Quality Management Systems (QMSs) play a key role in ensuring process stability and product conformity across the entire product life cycle [8–11]. At the same time, Lean Management has become a widely adopted approach for eliminating waste and improving operational efficiency [12–14]. Lean practices may also contribute to sustainability by improving manufacturing efficiency and reducing environmental impact, although these effects are often indirect and context-dependent [3,4,6,15–17].

Despite these developments, the integration of Lean Management with QMS and sustainability objectives remains insufficiently explored, particularly from a comprehensive and system-level perspective [3,5,15]. Existing research primarily focuses on operational performance improvements, with limited empirical evidence linking Lean-oriented improvement activities, QMS effectiveness, and measurable environmental outcomes in real industrial settings [6,18,19]. The lack of integrated approaches combining Lean, sustainability, and operational systems has been identified in the literature, together with limited empirical validation in industrial environments [15,20].

Existing studies reveal several limitations. Lean Management, QMS, and sustainability are often treated as loosely connected domains, while survey-based approaches provide limited insight into process-level operational relationships. The dominant reliance on survey-based data limits understanding of the relationships between process performance, system deficiencies, and environmental outcomes. Third, existing approaches often lack operationalization at the process level, which restricts their applicability in real industrial settings. As a result, there is a need for a data-driven and integrative analytical framework that explicitly links process variation, system-level deficiencies, and measurable sustainability effects.

The aim of this study is to examine how Lean-oriented practices and supporting quality management methods may contribute to process stability, defect reduction, and sustainability-related operational performance in a manufacturing environment. To achieve this aim, the study addresses the following research questions:

(1) What operational and system-level deficiencies limit process stability and quality performance within the analyzed QMS?
(2) Which Lean-oriented practices and supporting quality management methods may address the identified process deficiencies?
(3) How do the implemented operational improvements influence process stability, defect reduction, and estimated resource efficiency?

The study adopts a qualitative case study approach [18,21], including QMS assessment, identification of inefficiencies, and gap analysis against Lean requirements. Based on these findings, appropriate improvement methods and Lean-oriented practices were selected, and an implementation framework was developed, followed by an evaluation of operational and selected sustainability-related outcomes.

Unlike prior studies, the proposed approach integrates process variation analysis, QMS assessment, and improvement activities within a unified industrial evaluation structure. This approach addresses key limitations of existing research by providing both analytical depth and practical applicability.

The main contribution of this study lies in the operational integration of Lean-oriented practices, QMS assessment, SPC-based process analysis, and interpretation of potential environmental implications within a data-driven industrial case study. In particular, the study provides an empirical linkage between specific operational improvement practices, identified QMS deficiencies, and resource-related performance indicators. Unlike prior studies, the proposed approach operationalizes the relationship between process variation, QMS deficiencies, and improvement activities within a structured industrial analysis [3,5,15].

While Lean Management, QMS, and SPC are well-established in industrial practice, their application is often fragmented and lacks a consistent operational structure. This study does not introduce new individual Lean or quality management tools. Instead, its contribution lies in the structured integration of established industrial engineering methods within a unified analytical sequence applicable to real manufacturing environments.

In addition, the study extends conventional quality management approaches by introducing a quantitative linkage between defect rates and energy consumption. By treating defects as a proxy for quality-related energy losses, the proposed approach enables analytical estimation of potential environmental implications.

Although Lean–Green approaches have been widely discussed in the literature, they are typically conceptual or focused on high-level relationships between operational efficiency and sustainability performance. This study proposes a data-driven operational framework linking process instability, QMS deficiencies, and targeted improvement interventions supported by Lean-oriented practices and quality management methods.

Based on the identified research gaps, the study formulates the following research propositions in an operational form:

RP1: Process instability identified through SPC analysis may indicate underlying deficiencies in QMS implementation and operational control.

RP2: The integration of Lean-oriented practices and quality management methods may contribute to improved process stability and reduced defect rates.

RP3: Reduction in nonconforming products may contribute to lower quality-related energy losses in manufacturing systems.

These research propositions provide a structured basis for linking process performance, system-level management practices, and sustainability-related outcomes within the proposed analytical framework.

The research propositions are not tested using classical statistical inference but are evaluated through industrial data-driven validation, which is consistent with applied research in manufacturing systems.

The paper is structured as follows: Section 2 reviews the literature, Section 3 presents the methodology, Section 4 discusses the results, and Section 5 concludes the study.

2. Literature Review

2.1. Quality Management Systems in the Automotive Industry

Quality Management Systems (QMSs) are a fundamental component of operational excellence in the automotive industry, which is characterized by high process complexity, strict regulatory requirements, and low tolerance for defects [9,10]. There is a shift from compliance-based systems toward integrated operational frameworks supporting continuous improvement, risk management, and value creation [9,22].

Traditional quality management tools such as Statistical Process Control (SPC), Failure Mode and Effects Analysis (FMEA), and Advanced Product Quality Planning (APQP) remain essential for ensuring process capability and product conformity [1,23]. Statistical Process Control (SPC), originally developed within the Shewhart statistical quality framework, provides the methodological foundation for monitoring process stability and identifying assignable-cause variation in manufacturing systems. However, their effectiveness is limited when applied in isolation, particularly in complex and dynamically changing production environments [9,22].

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A gap between formal QMS implementation and operational performance has been identified. Certification according to ISO 9001 [24] does not necessarily result in improved process stability or defect reduction [10,11], indicating the need for stronger integration with operational practices and organizational culture [10,25].

Despite their structured nature, Quality Management Systems are also associated with several limitations. In particular, excessive formalization and documentation requirements may lead to bureaucratic rigidity, reducing responsiveness and limiting operational flexibility. Moreover, compliance-oriented QMS implementations often fail to translate into actual process improvements, as they focus on certification rather than performance. This creates a gap between formal system design and real operational effectiveness. These limitations suggest the need for stronger integration of QMS with operational improvement approaches such as Lean Management.

2.2. Lean Management as a Driver of Sustainable Manufacturing

Lean Management, derived from the Toyota Production System developed by Ohno and Shingo, has evolved from a production efficiency approach into a broader management philosophy supporting operational excellence and continuous improvement [1,12–14]. While traditionally focused on waste elimination, Lean is increasingly associated with improved operational efficiency and sustainability-related performance [3–6].

Lean-oriented practices and supporting methods such as Just-in-Time (JIT), Value Stream Mapping (VSM), and Total Productive Maintenance (TPM) contribute to reducing material waste, process variability, and energy consumption. SPC, RCA, and structured corrective methodologies are treated in this study as complementary quality engineering approaches. They are not classified as Lean tools in a strict theoretical sense [2,7,19,26]. Building on Lean–Green manufacturing research, several studies have linked operational waste reduction with environmental and resource-efficiency performance. This perspective extends traditional Lean thinking beyond productivity improvement toward sustainability-related outcomes [15,21,22].

However, the direct impact of Lean on sustainability remains debated. Significant potential resource-efficiency benefits have been reported [2,6]. These effects are often indirect and dependent on organizational and operational context [3,15,22]. This suggests that Lean-oriented improvement implementation alone may not be sufficient to achieve sustainability goals.

Despite its widely recognized benefits, Lean Management is subject to several limitations and ongoing debates. While Lean practices are associated with waste reduction and improved efficiency, their impact on sustainability is not inherently guaranteed. In some cases, efficiency improvements may lead to rebound effects, where increased productivity results in higher overall resource consumption. Furthermore, Lean-oriented improvement activities often prioritize operational performance over environmental objectives, unless explicitly aligned with sustainability strategies. Another limitation concerns the context-dependent nature of Lean outcomes, which vary depending on organizational maturity, leadership commitment, and system integration. These aspects highlight that Lean should not be treated as a universal solution but rather as a context-sensitive approach requiring integration with broader management systems.

Additionally, the integration of Lean with Industry 4.0 technologies has gained increasing attention. Digital solutions such as real-time monitoring and data analytics enhance process transparency and decision-making capabilities [2,18,25,27,28]. Nevertheless, empirical evidence on the combined impact of Lean and digitalization on sustainability remains limited [8,29,30].

Recent advances in Industry 4.0 and smart manufacturing increasingly combine Statistical Process Control with machine learning, predictive analytics, and explainable artificial intelligence (XAI) to enable proactive process monitoring and adaptive quality management. Unlike conventional SPC systems, which primarily support reactive detection of assignable-cause variation, AI-supported analytical systems may enable early anomaly prediction, automated pattern recognition, and dynamic process adaptation in real time. Although the present study focuses on conventional industrial engineering methods and SPC-based operational analysis, the proposed framework may provide a structured operational foundation for future integration with Industry 4.0 architectures and data-driven quality management systems.

Conceptual Classification of Lean and Supporting Quality Methods

To ensure conceptual consistency and avoid ambiguity in terminology, this study distinguishes between several complementary categories of operational improvement approaches.

First, Lean Management is treated as a broader managerial philosophy focused on waste reduction, continuous improvement, process flow optimization, and value creation.

Second, Lean managerial practices include organizational and behavioral approaches such as Gemba and Kaizen culture, which support employee involvement, operational transparency, and continuous improvement.

Third, Lean operational tools refer to specific process-oriented techniques supporting operational efficiency and process stability, including Standard Work, Visual Management, SMED, Poka-Yoke, and 5S.

Fourth, Quality Management System (QMS) methods include structured automotive and industrial quality approaches such as 8D, FMEA, APQP, and control plans. In this study, the 8D methodology is treated as an automotive quality-management and corrective-action approach rather than as a classical Lean/TPS operational tool.

Fifth, statistical quality control methods include Statistical Process Control (SPC), control charts, and process capability analysis, which support process monitoring and variability assessment.

Finally, root cause analysis (RCA) techniques include analytical problem-solving methods such as 5Why analysis, Ishikawa diagrams, and Fault Tree Analysis (FTA).

In the context of this study, these categories are treated as complementary but conceptually distinct components of an integrated industrial improvement system rather than as homogeneous improvement interventions.

The classification adopted in this study is consistent with established Lean and operational excellence literature, including Toyota Production System principles, SAE J4000/J4001 [31] operational criteria, and Lean maturity assessment frameworks. These approaches distinguish between Lean philosophy, operational practices, quality-management methodologies, statistical quality methods, and root cause analysis techniques.

The categorization of Lean-oriented requirements and supporting methods adopted in this study was developed based on established operational excellence and Lean assessment frameworks.

Similar categorizations are discussed within the Toyota Production System literature, Lean maturity assessment models, and industrial operational excellence frameworks. In particular, the classification was informed by the Toyota Production System (TPS) principles, SAE J4000/J4001 Lean Operations standards [31], Lean maturity assessment models, and industrial operational excellence frameworks emphasizing process stability, standardization, visual management, employee involvement, and continuous improvement. These frameworks collectively support the distinction between Lean managerial practices, Lean operational tools, statistical quality methods, QMS methodologies, and root cause analysis techniques. The classification structure was subsequently adapted to the operational characteristics of the analyzed industrial case study.

2.3. Integration of Lean Management, QMS, and Sustainability

Despite growing research interest, the integration of Lean Management, QMS, and sustainability remains limited. Most studies focus on pairwise relationships, such as Lean and operational performance [3,14,19], Lean and environmental outcomes [17,27,31], or QMS and quality performance [8,11], without adopting a system-level perspective.

In the automotive and manufacturing sectors, Lean practices are widely recognized for improving efficiency and reducing waste; however, their interaction with QMS and their contribution to systemic quality improvements are rarely analyzed [3,18]. Barriers include organizational resistance, lack of standardization, and insufficient strategic alignment [18,22].

Importantly, there is limited empirical research linking specific operational methods with identified deficiencies in QMS and measurable sustainability-related implications, such as reduced resource consumption or waste reduction. Moreover, the dominance of survey-based studies limits insight into real-world implementation processes and reduces the explanatory power of findings [18,21,31].

The integration of Lean Management, QMS, and sustainability is also characterized by conceptual ambiguity and limited theoretical consensus. While some studies treat Lean as a driver of sustainability, others argue that its impact is indirect and contingent upon implementation context. Additionally, there is no unified analytical framework explaining how process-level improvements translate into system-level sustainability-related implications. This lack of theoretical clarity results in fragmented approaches and limits the ability to generalize findings. Consequently, there is a need for integrative models that explicitly define operational relationships between operational practices, system-level structures, and sustainability performance.

From a theoretical perspective, the proposed approach combines three complementary analytical traditions: (1) statistical process stability derived from SPC theory, (2) continuous improvement and waste elimination associated with Lean/TPS philosophy, and (3) system-oriented quality governance embedded in QMS frameworks. While these perspectives are commonly discussed independently in the literature, the present study operationally integrates them within a unified industrial analytical sequence linking process instability, system-level deficiencies, operational interventions, and sustainability-related outcomes.

2.4. Research Gap and Scientific Contribution

The importance of integrating Lean Management, QMS, and sustainability has been widely discussed. First, existing research predominantly focuses on pairwise relationships (e.g., Lean–performance or Lean–environment), while system-level integration linking process performance, QMS deficiencies, and improvement tools remains underdeveloped. Second, although Statistical Process Control (SPC) is widely applied for process monitoring, its role is typically limited to operational control and delayed post-occurrence detection [32].

Traditional SPC systems primarily support reactive process monitoring based on predefined control limits and post-occurrence detection of assignable-cause variation. In contrast, recent Industry 4.0 approaches increasingly utilize adaptive and threshold-free analytical architectures supported by machine learning, automated clustering, and predictive quality analytics. These approaches may improve responsiveness by enabling early detection of process anomalies, dynamic process adaptation, and machine-specific pattern recognition beyond the capabilities of conventional manual SPC interpretation. Nevertheless, despite the growing importance of AI-supported quality systems, conventional

SPC-based industrial analysis remains widely applied in manufacturing practice due to its interpretability, operational simplicity, and compatibility with existing QMS structures.

There is a lack of studies that connect SPC-based detection of operational variability with system-level QMS deficiencies and targeted improvement interventions supported by Lean-oriented practices and quality management methods in real industrial environments. Third, the relationship between quality improvement and sustainability-related implications—particularly energy efficiency—remains largely conceptual, with limited empirical or analytical models linking defect reduction and process stabilization to resource and energy performance. Finally, much of the existing literature relies on survey-based or conceptual approaches, providing limited insight into analytical relationships and implementation pathways in real manufacturing systems. To address these gaps, this study proposes an integrated Lean–QMS analytical framework supported by statistical process analysis that links:

- Data-driven identification of assignable-cause variation;
- System-level diagnosis of QMS deficiencies;
- Targeted selection of improvement activities.

This framework extends the analysis toward material and energy performance and energy-related implications of process improvement.

From a methodological perspective, the existing body of literature is dominated by survey-based and perceptual studies, which provide limited insight into analytical relationships. There is a lack of data-driven and process-oriented analyses that would enable a deeper understanding of how specific operational interventions influence both quality performance and sustainability-related implications. This limitation reduces the explanatory power of existing models and highlights the need for empirical, case-based research supported by quantitative process data.

In contrast to existing studies, the proposed framework integrates SPC-based process monitoring, root cause analysis, QMS gap assessment, and Lean-oriented improvement activities within a structured industrial evaluation sequence. The contribution of the study lies primarily in the operationalization and industrial application of these complementary methods in a unified analytical context rather than in the development of fundamentally new theoretical constructs.

Accordingly, the theoretical contribution of the study lies in operationally linking SPC-based instability detection, QMS deficiencies, root-cause structures, and Lean-oriented improvement interventions within a process-oriented analytical framework.

The proposed analytical approach may also support future digitalization initiatives by providing a structured basis for process monitoring, root cause identification, and data-driven operational improvement. However, the present study focuses on the integration of established industrial engineering methods within a conventional manufacturing environment rather than on advanced AI-based process control.

3. Materials and Methods

3.1. Case Study Selection and Justification

The effectiveness of Quality Management Systems (QMSs) and Lean-oriented improvement implementation depends strongly on the organizational and operational context [33]. Therefore, a qualitative case study approach was adopted to investigate the integration of process improvement approaches with QMS in a real manufacturing environment.

The selected case represents a large-scale production system with high process variability and strict quality requirements. The study is based on an industrially grounded model developed using real production data, engineering practices, and domain expertise. While certain elements were anonymized to ensure confidentiality, the structure and relationships reflect actual industrial conditions.

This approach enables a comprehensive analysis of interactions between process performance and system-level management practices. It also supports the evaluation of resource-efficiency outcomes. The purpose of this section is to provide a realistic foundation for the subsequent analysis of Lean-oriented improvement implementation in the context of QMS improvement.

The case study strategy was selected due to its suitability for in-depth investigation of complex, real-world phenomena where contextual conditions play a significant role. This approach allows for analytical generalization rather than statistical generalization, which is consistent with research focused on understanding operational interaction in industrial systems.

3.2. Company Profile and Production System

The analyzed case represents a high-volume automotive manufacturing system characterized by high product variability, strict dimensional requirements, and multi-stage production processes. The production environment includes automated and semi-automated operations and operates under Just-in-Time delivery constraints. These characteristics make the system suitable for analyzing the interaction between process stability, QMS effectiveness, and Lean-oriented improvement activities [34,35].

The production process is organized as a linear flow and includes forming, joining, component manufacturing, surface treatment, assembly, and quality inspection. Both automated and semi-automated technologies are used to ensure process repeatability and consistency.

The analyzed system represents a high-volume manufacturing environment operating within a global supply chain. The production system is characterized by:

- High product variability;
- Dynamic customer requirements;
- Strict quality standards;
- Multi-stage production processes;
- Just-in-Time (JIT) delivery constraints.

Overall, the system is characterized by high process complexity and strict quality requirements, making it suitable for analyzing the integration of Lean Management and QMS.

3.3. Quality Management System Description

The company operates a certified Quality Management System compliant with ISO 9001:2015 [24] and IATF 16949:2016 standards [36]. The system follows a process-oriented approach, including defined responsibilities, procedures, and control mechanisms. Core elements include process documentation, operational instructions, inspection plans, and quality tools such as FMEA, control plans, and process flow diagrams [37]. Quality control is implemented throughout production using standardized measurement procedures and appropriate equipment, supporting process capability analysis and performance monitoring. The system also includes structured non-conformance management (e.g., 8D methodology), internal audits, and employee training programs to ensure process compliance and continuous improvement.

Despite its structured design, preliminary observations indicate inefficiencies related to process integration, data utilization, and operational discipline. These limitations provide a basis for further analysis using Lean Management principles.

3.4. Research Methodology

3.4.1. Research Design

This study adopts an applied research design aimed at addressing practical challenges in manufacturing systems while contributing to theoretical development. From a methodological perspective, the research follows a case study approach, combining qualitative and quantitative methods. The qualitative component focuses on system-level assessment, process observation, and identification of organizational and operational deficiencies, while the quantitative component is based on statistical process analysis and performance measurement.

In terms of research objective, the study is both exploratory and explanatory. It is exploratory in identifying gaps in the existing Quality Management System (QMS) and potential areas for Lean-oriented improvement implementation, and explanatory in analyzing the operational relationships between process instability, system deficiencies, and performance outcomes. This dual perspective enables a comprehensive understanding of the studied phenomenon.

The case study approach was selected due to its suitability for analyzing complex, real-world industrial systems characterized by high process variability, multiple interdependencies, and context-specific constraints.

The research design combines qualitative assessment with quantitative analysis to evaluate organizational conditions and process performance within the analyzed manufacturing system. This industrial context provides a representative environment for analyzing the interaction between Lean-oriented operational practices, QMS performance, and sustainability-related outcomes.

3.4.2. Analytical Procedure

The research procedure was structured into four main stages:

1. Assessment of the Current QMS State

A comprehensive evaluation of the existing QMS was conducted, including:

- Process documentation analysis;
- Observation of production practices;
- Evaluation of quality control systems;
- Identification of inefficiencies and non-value-adding activities.

2. Definition of Lean-Oriented Improvement Activities Requirements

Based on Lean assessment frameworks discussed in the literature, including TPS principles, SAE J4000/J4001 [31] operational criteria, and Lean maturity models, the key implementation requirements were categorized into:

- Organizational structure;
- Documentation and standardization;
- Process monitoring;
- Organizational culture.

3. Gap Analysis (QMS vs. Lean Requirements)

A structured comparison between the current system and Lean requirements was performed to identify:

- Structural gaps;
- Process inefficiencies;
- Limitations in data utilization;
- Cultural barriers.

4. Root Cause Analysis and Tool Selection

Identified problems were further analyzed using quality management tools to determine their root causes and to support the selection of appropriate operational methods. Figure 1 shows the test procedure.

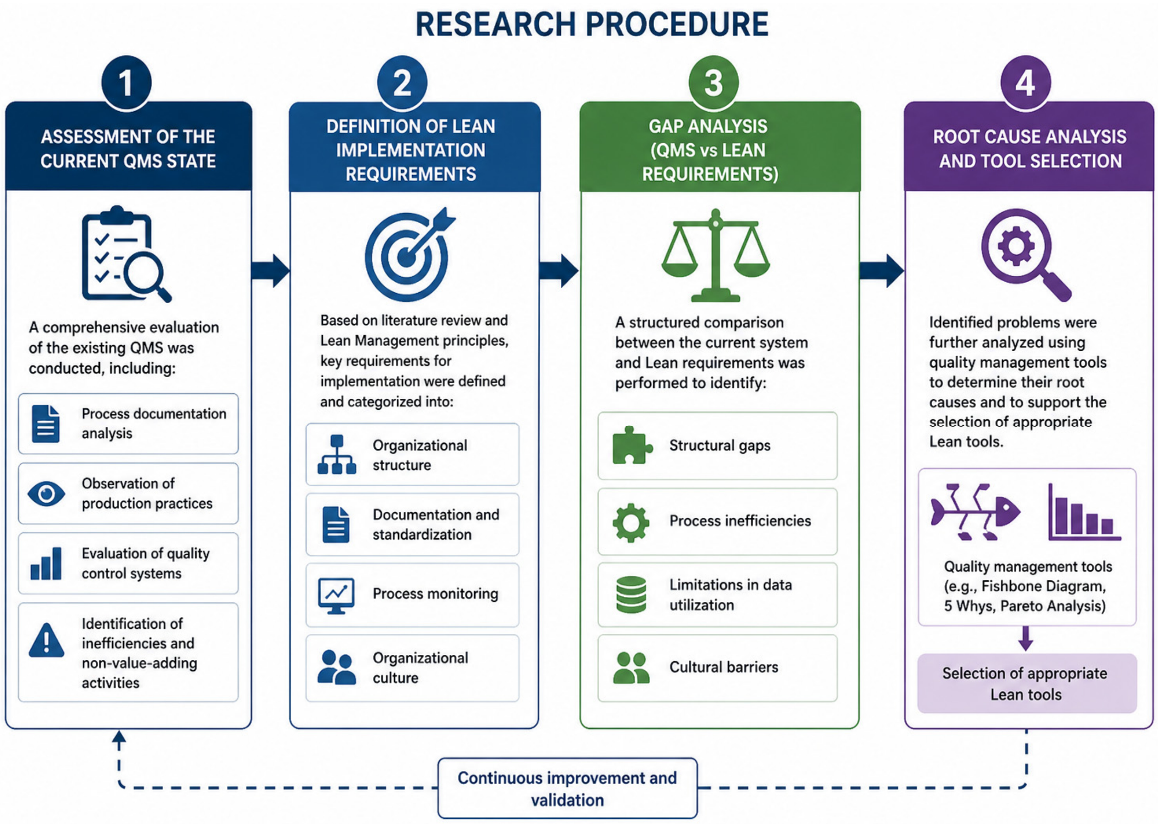

Figure 1. Conceptual and empirical sequence of the integrated Lean–QMS–SPC analytical approach. Source: own elaboration.

The study integrates both qualitative and quantitative data to ensure methodological robustness and analytical reliability. The integration of qualitative and quantitative methods follows a mixed-methods research logic, where qualitative insights support the interpretation of quantitative results, and statistical analysis provides empirical validation of observed relationships. Accordingly, the study emphasizes analytical interpretation and industrial validation rather than hypothesis testing in a strict inferential statistical sense. This methodological triangulation enhances the robustness and credibility of the findings.

3.4.3. Qualitative Assessment

Qualitative methods:

- Process observation;
- Document analysis (QMS documentation, procedures);
- Evaluation of organizational practices.

Quantitative methods:

- Statistical process analysis;
- Control charts (Shewhart);
- Process capability analysis;
- Defect and variability assessment.

To identify root causes of waste and quality issues, the following tools were applied:

- Pareto analysis;

- 5Why method;
- Ishikawa diagram;
- 5W2H method;
- Structured Action Planning.

The analyzed parameter represents a special characteristic (A25 ± 0.50 mm), corresponding to the distance between mounting hole axes in an automotive structural component.

Process stability was evaluated using Shewhart control charts, while variability and capability were assessed through statistical indicators. This analysis enabled:

- Identification of operational variability;
- Detection of out-of-control conditions;
- Verification of the presence of assignable causes.

The final stage involved linking identified QMS deficiencies with appropriate Lean-oriented practices, quality management methods, statistical process control techniques, and root cause analysis approaches. A structured mapping approach was applied, enabling:

- Alignment of operational improvement practices with specific process deficiencies;
- Development of an implementation sequence;
- Evaluation of potential improvements in terms of quality performance and sustainability indicators (e.g., waste reduction, operational efficiency).

All figures and tables presented in this study are based on the authors' own elaboration using empirical production and quality data collected during the case study.

3.4.4. Quantitative and SPC Analysis

Therefore, the applied statistical approach focuses on process behavior rather than hypothesis testing in a classical statistical sense. The dataset used for statistical analysis consisted of measurements collected from 33 subgroups, each containing 8 observations, resulting in a total of 264 data points. The analyzed characteristic (A25 ± 0.50 mm) represents a critical-to-quality dimension in an automotive component. Data were collected under standard production conditions and are assumed to follow an approximately normal distribution, which is a common assumption in SPC-based analysis.

To support analytical interpretation of the research propositions, the study applies a comparative before–after analysis. Assignable-cause variation is evaluated based on control chart signals (out-of-control points). Process performance is assessed using capability indices (*Cp*, *Cpk*) and defect rate (ppm), while resource-efficiency-related effects are analytically estimated through changes in estimated energy consumption associated with defective units.

3.4.5. Statistical Validation

This limitation is acknowledged, and future research should incorporate formal statistical validation of distributional assumptions to enhance analytical rigor.

To enhance the statistical rigor of the analysis, an additional validation step was performed. The normality of the process data was assessed using the Shapiro–Wilk test, which is widely recommended for small and medium-sized datasets. The results indicated no significant deviation from normality ($p > 0.05$), supporting the validity of applying SPC-based capability analysis.

Furthermore, to evaluate the statistical significance of process improvement, a comparative analysis of process performance before and after Lean-oriented improvement implementation was conducted. A two-sample *t*-test was applied to compare the mean values, while an F-test was used to assess differences in variance.

The comparative analysis indicated a measurable reduction in process variability ($p < 0.05$), as well as a shift toward improved process centering. These findings support the interpretation that the observed improvements were associated with the implemented operational improvement interventions.

The additional statistical tests were introduced solely to support robustness of process comparison and should not be interpreted as full inferential hypothesis testing.

Although the statistical validation is limited by the case study nature of the research, the applied tests provide additional support for the robustness of the findings.

Therefore, the study combines established industrial engineering methods (SPC, RCA, Lean-oriented practices and supporting methods) to provide a practical and data-driven evaluation of process performance and improvement potential. This enables both practical applicability and applied methodological contribution.

It should be noted that process performance indicators (SPC results, process capability indices, and defect rates) are derived from actual industrial data collected during production. In contrast, the analysis of energy consumption and CO_2 emissions is based on a scenario-driven estimation model. This model uses empirically observed defect rates combined with standard industrial parameters to evaluate the potential impact of process improvements on energy efficiency.

3.5. Analytical Framework

The framework was conceptually derived from established Lean Management, QMS, and industrial engineering literature prior to empirical application within the analyzed manufacturing environment. The case study served as an operational illustration and quantitative validation within a single industrial context rather than as the sole basis for framework development.

To improve methodological consistency and operational clarity, an analytical framework was formulated based on established industrial engineering methods identified in the literature and subsequently applied within the analyzed case study:

1. Process performance evaluation using Statistical Process Control (SPC).
2. System-level assessment of QMS gaps.
3. Targeted selection of Lean-oriented operational practices and supporting analytical methods.
4. The proposed framework follows a structured analytical sequence:
    - Detection of unstable process conditions (SPC);
    - Identification of root causes (RCA);
    - Mapping of system deficiencies (QMS gap analysis);
    - Selection of appropriate improvement interventions;
    - Evaluation of operational and resource-efficiency outcomes.

These parameter values are based on typical ranges reported in industrial practice and literature on energy consumption in manufacturing systems. This analytical sequence integrates a structured basis for interpreting relationships between process stability, quality performance, and resource-efficiency-related implications. As illustrated in Figure 2, the proposed framework integrates statistical process evaluation, root cause analysis, and system-level gap identification with targeted Lean tool selection.

The framework was conceptually derived from established industrial engineering and Lean assessment literature prior to empirical application within the case study environment. The case study served as an operational illustration and quantitative validation within a single case study context.

Although the individual components are well established in industrial practice, their integration within a unified operational framework and extension toward estimated energy-related implications represent the primary applied contribution of this study. The proposed framework integrates a consistent basis for linking process stability, quality performance, and estimated sustainability implications.

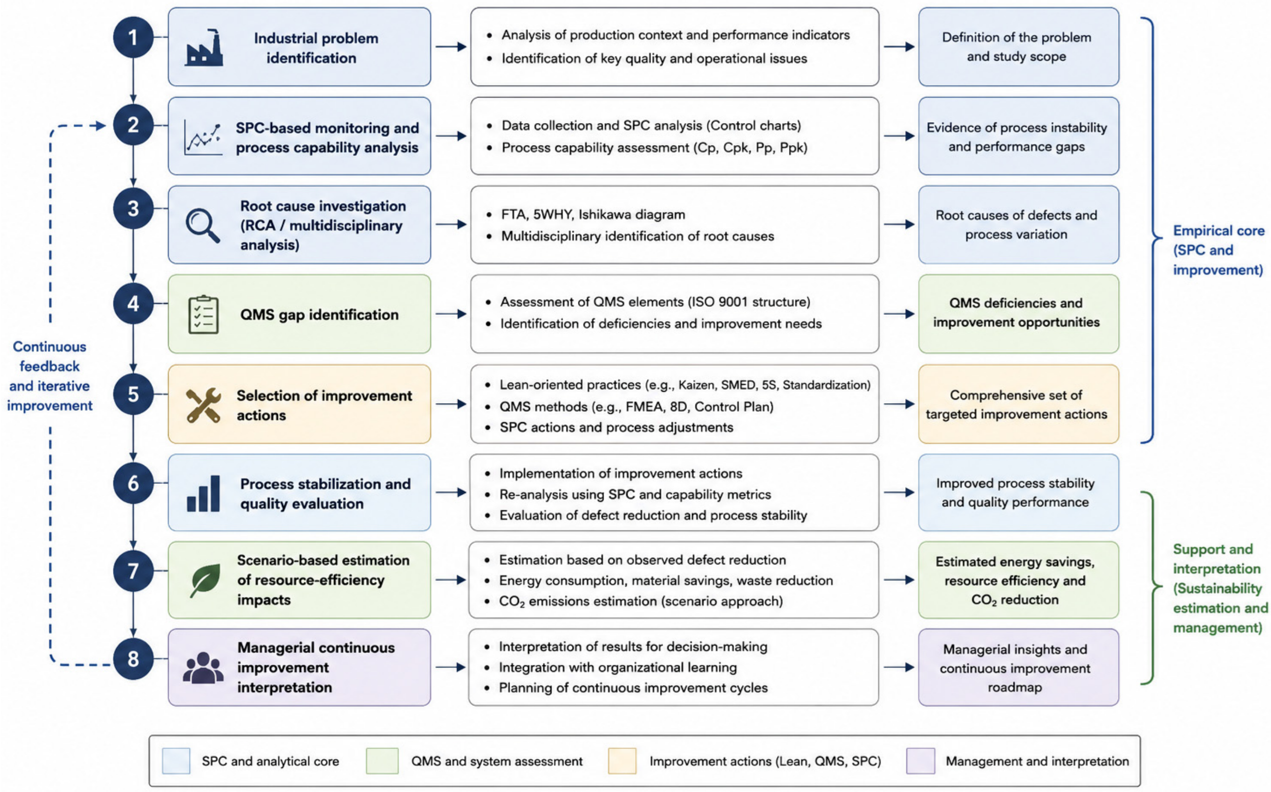

Figure 2. Methodological sequence of the integrated SPC–QMS–Lean analytical framework applied in the industrial case study [24]. Source: own elaboration.

Rather, it represents a structured operational integration of established Lean-oriented practices, quality management methods, SPC-based process analysis, and root cause identification techniques within a real industrial environment.

4. Results

4.1. Analysis of the Possibility of Implementing Lean Management Tools

The results are presented in relation to the research questions defined in Section 1. In particular, the analysis addresses:

(RQ1) Identification of gaps in the existing Quality Management System (QMS);

(RQ2) Selection and implementation of appropriate improvement activities;

(RQ3) Evaluation of their impact on process performance and resource efficiency.

The implementation of Lean-oriented practices supported by quality management methods and statistical process analysis requires the fulfillment of specific organizational, process-related, and cultural conditions [34].

To systematically assess implementation readiness, the requirements were classified into four key categories: organizational structure, documentation and standardization, process monitoring, and organizational culture. These categories were derived from the literature and subsequently operationalized and applied to the analyzed case study.

First, a clearly defined organizational structure with assigned responsibilities is important for effective quality management and rapid response to non-conformities. The presence of trained personnel, interdisciplinary collaboration, and employee involvement in continuous improvement initiatives enables the successful deployment of operational methods such as Kaizen [35,36].

Second, standardized and unified quality documentation supports data consistency and improves decision-making processes. Reducing documentation complexity enhances operational efficiency and enables the effective application of Lean practices, including standard work, visual management, and layered audits [37–39].

Third, effective process monitoring and real-time response mechanisms support process stability and facilitate faster reaction to operational deviations. SPC supports data-driven process control and operational quality stabilization within integrated improvement systems [39].

Finally, an organizational culture focused on quality and continuous improvement supports long-term operational improvement and organizational learning [40].

In summary, the effectiveness of Lean-oriented improvement implementation within QMS is strongly dependent on the organization's maturity level. The identified requirement categories constitute a structured evaluation framework for assessing implementation readiness and were subsequently used to assess the analyzed production system.

4.2. Identified QMS Gaps and Lean-Oriented Improvement Implementation Potential

The conducted case study analysis revealed several critical gaps in the existing Quality Management System (QMS), which limit process efficiency, quality performance, and the organization's ability to improve operational and resource-efficiency performance.

First, significant deficiencies were identified in the area of organizational structure and responsibility. The lack of clearly assigned ownership for quality-related issues and limited employee involvement resulted in delayed responses to non-conformities and reduced effectiveness of corrective actions. This indicates insufficient support for continuous improvement practices and highlights the need for structured team-based problem-solving approaches.

Second, gaps in employee competencies and training were observed. In particular, limited knowledge of root cause analysis methods and quality tools contributed to recurring defects and ineffective problem resolution. The results indicate insufficient workforce capability in root cause analysis methods.

Third, the QMS was characterized by fragmented and inconsistent documentation. The lack of standardization and excessive complexity of quality records hindered data interpretation and reduced operational efficiency. This issue was particularly evident in high-volume production environments, where large datasets must be processed within short timeframes.

Deficiencies in process monitoring and data management were identified. The absence of real-time data analysis and the limited use of statistical methods resulted in the delayed detection of process deviations and a predominantly reactive approach to quality management. This reduces the organization's ability to prevent defects and optimize process performance.

Another critical gap concerned the response to non-conformities. The analysis indicated the absence of standardized escalation procedures and delays in implementing corrective actions, which contributed to increased scrap rates and customer complaints.

In addition, the organizational culture was found to be insufficiently oriented toward quality and continuous improvement. Limited transparency in communication and a tendency to avoid reporting errors hindered organizational learning and the identification of improvement opportunities.

Finally, a lack of integration between QMS processes and production flow was identified. Silo-based decision-making and weak coordination between departments resulted in duplicated activities and reduced overall system efficiency. Moreover, sustainability-related aspects, such as reduced resource consumption and waste reduction, were not systematically integrated into the QMS operational framework.

These deficiencies collectively indicate that the current system operates in a reactive mode, limiting its capability to support proactive, Lean-oriented quality management. Based on these findings, the potential for Lean-oriented improvement implementation was evaluated by linking identified gaps with appropriate improvement activities and practices (Table 1).

Table 1. Alignment of Lean Management Requirements with Identified QMS Gaps.

Lean Requirement Category	Key Requirement	Identified QMS Gap	Impact on Performance	Recommended Improvement Method/Practice	Classification	Theoretical Basis
Organizational Structure and Responsibility	Clear assignment of responsibilities; employee involvement	Lack of ownership; low engagement	Delayed corrective actions	Kaizen (Lean managerial practice), 8D (automotive QMS problem-solving methodology	Lean managerial practices	TPS/Continuous Improvement
Competence and Training	Skills in quality tools and problem-solving	Insufficient knowledge of RCA methods	Recurring defects	5Why, Ishikawa	RCA technique	Toyota Production System (TPS)
Documentation and Standardization	Unified and simplified documentation	Fragmented and inconsistent records	Errors in data interpretation	Standard Work, 5S, Visual Management	Lean operational tools	Lean flow management
Process Monitoring and Data Management	Real-time monitoring and KPI tracking	Lack of real-time analysis	Reactive management	SPC	Statistical quality methods	Shewhart/QMS
Response to Non-Conformities	Fast and structured corrective actions	Delays and lack of escalation procedures	Increased scrap and complaints	A3, 8D	QMS problem-solving methodologies	Automotive QMS/IATF
Organizational Culture	Continuous improvement mindset	Low transparency	Hidden problems	Kaizen culture, Gemba	Lean managerial practices	TPS/Continuous Improvement
Process Integration	Alignment between QMS and production flow	Silo-based decisions	Inefficiencies	VSM	Lean process analysis tools	Lean flow management
Sustainability Orientation	Waste reduction and resource efficiency	Lack of environmental integration	Higher resource consumption	Sustainability-oriented operational practices	Sustainability-oriented practices	Lean–Green manufacturing literature

Source: Authors' elaboration.

The identified deficiencies in organizational structure, process monitoring, documentation, and system integration directly address RQ1, confirming the presence of significant gaps in the existing QMS that limit process efficiency and hinder the organization's ability to improve operational and resource-efficiency performance.

4.3. Verification of Lean-Oriented Improvement Implementation Requirements in the Case Study Company

To further operationalize the identified gaps, a detailed verification was conducted. This evaluation enabled a more detailed assessment of the organization's readiness for Lean deployment (Table 2).

Table 2. Verification of Lean-oriented improvement implementation Requirements in the Case Study.

Current QMS State	Lean-Oriented Improvement Implementation Requirement	Identified Gap	Recommended Improvement Method/Practice	Classification	Theoretical Basis
Extensive documentation (ERP + spreadsheets); basic quality tools	Standardization and real-time integration	Fragmented data; lack of linkage with RCA	Standard Work, Digitalization, Visual Management	Lean operational tools	Lean flow management
In-process and final inspections; capability analysis	Real-time monitoring and fast response	Delayed reaction; lack of prioritization	SPC	Statistical quality methods	Shewhart/QMS
Non-conformance management (8D, segregation)	Proactive problem-solving system	Reactive approach	A3, 8D	QMS problem-solving methodologies	Automotive QMS/IATF
Internal audits (VDA 6.3)	Risk-based prevention	Focus on compliance	LPA, risk analysis	QMS auditing methodologies	IATF 16949 [36] layered process auditing
Training system	Continuous improvement culture	Lack of employee involvement	Kaizen system	Lean managerial practices	TPS/Continuous Improvement

Source: Authors' elaboration.

Despite a relatively high level of QMS maturity, the analysis identified several critical limitations. The most significant deficiencies were identified in the area of data integration and documentation management. Although the company maintains extensive documentation supported by ERP systems and spreadsheet-based tools, the lack of integration with root cause analysis limits real-time decision-making and reduces problem-solving efficiency.

Furthermore, process monitoring remains largely reactive. Quality data are collected and analyzed; however, decision-making is primarily based on periodic evaluations, which delays the detection of deviations and prevents effective prioritization of critical issues.

A similar pattern was observed in non-conformance management and audit practices. While structured procedures such as 8D and VDA 6.3 audits are implemented, they are predominantly focused on compliance and post-event analysis rather than proactive risk prevention.

In the area of human resources, the organization demonstrates a structured approach to training. However, the absence of formal mechanisms supporting employee involvement in continuous improvement significantly limits the development of a Lean-oriented culture.

Overall, the results indicate that the analyzed QMS provides a solid operational foundation but requires structural improvements to enable effective Lean integration and support sustainable manufacturing objectives.

To further investigate the sources of variability identified in the gap analysis, a detailed statistical and root cause analysis was conducted, focusing on process stability, capability, and underlying causes of variation.

The verification results further support RQ1 by demonstrating that, despite formal system maturity, critical limitations exist in data integration, real-time monitoring, and proactive quality management.

4.4. Root Cause Analysis of Waste in the Case Study Company

The next stage of the analysis focused on identifying the root causes of quality-related problems to support the selection of targeted operational improvement measures. This step is essential to ensure that improvement actions address actual sources of inefficiencies rather than their symptoms. A structured analytical approach was adopted, combining Statistical Process Control (SPC) with qualitative root cause identification methods. SPC analysis was applied to identify assignable-cause variation and evaluate process stability within the analyzed manufacturing system [40,41]. The analysis included control charts, process capability assessment, and problem-solving tools such as Fault Tree Analysis (FTA), 5WHY, and the Ishikawa diagram. This multi-method approach enabled a comprehensive evaluation of process performance across technical, organizational, and systemic dimensions. A detailed statistical analysis was conducted for a selected critical quality characteristic (A25 $\pm$ 0.50 mm), representing the distance between mounting hole axes in an automotive structural component. Table 3 presents measurements for 24 representative subgroups extracted from the complete dataset, consisting of 33 subgroups with 8 observations each. Due to space limitations, Table 3 presents a representative subset of the complete measurement dataset used in SPC analysis. The full statistical analysis presented in Tables 4 and 5 and the corresponding control charts was conducted using 33 subgroups with 8 observations each.

Table 3. Measurement test of the L1 characteristic.

Lp.	P1	P2	P3	P4	P5	P6	P7	P8
1	24.92275	24.97491	24.92130	25.14850	25.01605	24.85879	25.05360	24.85807
2	25.22240	24.92178	25.00500	25.07508	24.96839	24.94562	25.08181	24.88229
3	25.07161	24.81500	24.81909	24.94126	24.7139	24.95522	24.87693	24.99384
4	24.98112	25.09196	24.89405	25.08060	24.99279	24.93605	25.01657	24.90766
5	24.95419	24.9600	25.0389	25.00644	24.78483	25.17724	25.2093	24.94882
6	25.21321	25.18260	25.0744	25.09880	25.23906	24.94446	25.21122	25.25860
7	25.01812	25.25040	25.17579	25.20907	25.07815	24.97464	25.04711	24.83989
8	24.92610	25.09046	24.92362	25.05918	25.24023	24.95821	25.05387	24.84762
9	25.16534	25.16486	24.99000	24.95598	25.01368	24.9245	25.12192	25.17771

Table 3. *Cont.*

Lp.	P1	P2	P3	P4	P5	P6	P7	P8
10	25.05091	24.83896	25.21328	25.09066	25.06340	24.86066	25.02548	25.04271
11	24.99432	25.04634	24.89002	24.92942	24.89922	24.95752	24.78203	25.08802
12	24.82229	24.78747	24.89552	24.84100	24.72770	24.78365	24.74207	24.97951
13	24.96932	25.00228	25.24229	25.09934	25.04342	24.88719	24.87642	24.87535
14	25.11376	25.13092	25.12502	24.92407	24.87050	25.03713	25.07969	25.05091
15	25.12534	25.13082	25.17826	25.12664	24.86242	24.96530	25.01556	25.24298
16	24.87700	24.91927	24.92883	25.03123	24.91862	24.98448	24.80104	24.96398
17	25.28890	25.04358	25.49739	25.12096	25.48675	25.27620	25.28112	25.31106
18	24.95783	24.97102	25.10949	25.22619	25.02578	24.92419	25.17269	25.00274
19	24.98536	24.76816	25.01504	25.09559	24.91865	25.12684	24.91442	24.95958
20	24.91431	24.92049	24.85488	24.98035	24.97252	24.98406	25.03848	24.83246
21	25.15714	25.1678	25.08618	25.16721	25.09581	25.30341	25.22264	25.19438
22	24.87622	25.02732	25.10377	25.13173	25.02147	25.24858	25.07954	24.96186
23	24.73130	24.81466	24.71339	24.59823	24.79039	24.77810	24.75309	24.87536
24	25.09246	25.16858	25.12603	24.95916	25.19678	25.24255	25.27100	25.11285

Source: Authors' elaboration.

Table 4. Expected value and standard deviation for the X¯-S card.

Component	X¯	S	Component	X¯	S
1	24.97589	0.106475	18	25.06173	0.110724
2	24.98285	0.075528	19	24.97118	0.121765
3	24.87361	0.097993	20	24.94046	0.074738
4	24.98853	0.079790	21	25.17678	0.074592
5	25.01793	0.144362	22	25.08204	0.092906
6	25.14416	0.111715	23	24.76046	0.087499
7	25.08215	0.144153	24	25.15385	0.103289
8	25.02474	0.128330	25	25.04052	0.050862
9	25.04981	0.103425	26	25.02749	0.124106
10	25.01931	0.130984	27	25.04651	0.100724
11	24.94180	0.102250	28	25.02192	0.129645
12	24.82242	0.089926	29	25.06041	0.064361
13	25.00376	0.137779	30	24.98039	0.098480
14	25.03118	0.099015	31	24.99042	0.079248
15	25.07457	0.132550	32	24.99668	0.122854
16	24.93535	0.071934	33	24.98541	0.136594
17	25.28815	0.169167			

Source: Authors' elaboration.

For each subgroup, the mean value (X¯), standard deviation (S), and range (R) were calculated (Tables 4 and 5).

In accordance with statistical process control (SPC) principles, X¯–S and X¯–R control charts were constructed to evaluate process stability. Control limits were determined using standard SPC formulas, with the upper control limit (UCL), lower control limit (LCL), and central line (CL) calculated based on subgroup statistics and constants specific to the subgroup size. Control limits (UCL/LCL) are derived from process data and are used to assess process stability, whereas specification limits (USL/LSL) represent customer requirements and are applied in process capability analysis. These two concepts were considered separately in this study [42].

Table 5. Expected value and range for the $\bar{X}$-R card.

Component	$\bar{X}$	R	Component	$\bar{X}$	R
1	24.969248	0.2904296	18	25.048740	0.3020024
2	25.012797	0.3401080	19	24.972957	0.3586724
3	24.898356	0.3577115	20	24.937193	0.2060210
4	24.987601	0.1979059	21	25.174322	0.2172311
5	25.009963	0.4244724	22	25.056311	0.3723636
6	25.152793	0.3141416	23	24.756815	0.2771362
7	25.074146	0.4105181	24	25.146176	0.3118407
8	25.012411	0.3926101	25	25.070506	0.3144758
9	25.064249	0.2532035	26	25.034256	0.3517202
10	25.023258	0.3743206	27	25.058688	0.2447996
11	24.948360	0.3059857	28	25.035515	0.3426070
12	24.822402	0.2518119	29	25.067311	0.1829752
13	24.999452	0.3669335	30	24.994595	0.2893707
14	25.041501	0.2604250	31	24.976721	0.2433471
15	25.080914	0.3805596	32	24.971722	0.4426145
16	24.928058	0.2301915	33	24.986748	0.3650090
17	25.288246	0.4538081			

Source: Authors' elaboration.

The $\bar{X}$ control charts (Figure 3) indicate the presence of multiple points exceeding the control limits, confirming the occurrence of special cause variation. Specifically, four subgroups exceeded the control limits in the $\bar{X}$–S chart, while seven such violations were observed in the $\bar{X}$–R chart. These results demonstrate that the analyzed process is not statistically controlled (Table 6).

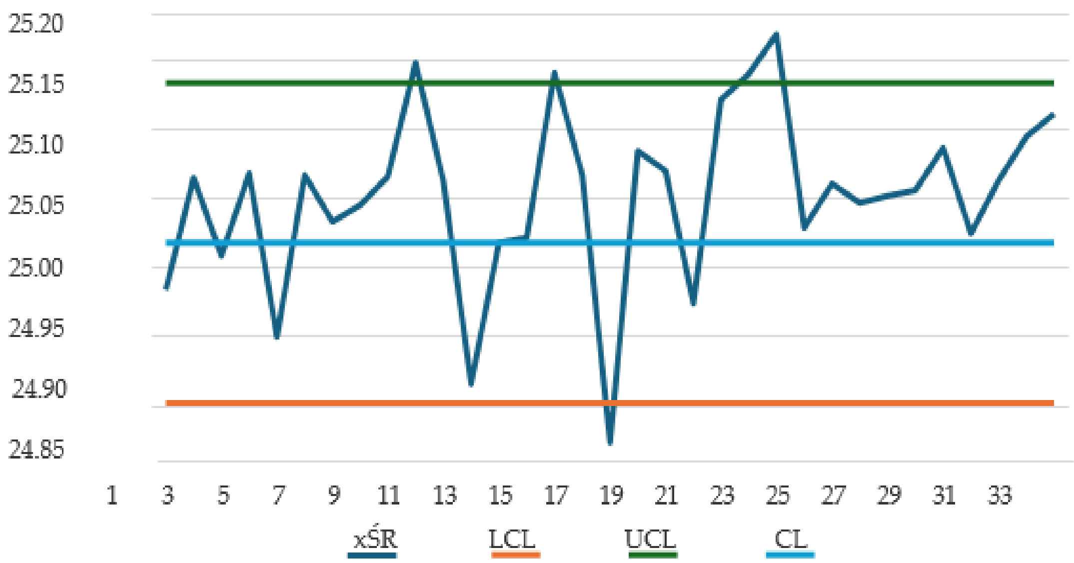

Figure 3. $\bar{X}$ control chart indicating the occurrence of assignable-cause variation. Source: Authors' elaboration.

Table 6. Upper and lower control limits for the $\bar{X}$1 chart.

	$\bar{X}$	
UCL	**LCL**	**CL**
25.13408	24.90243	25.01825

Source: Authors' elaboration.

In contrast, the S chart (Figure 4) shows that all observations remain within control limits, indicating relatively stable process dispersion. This indicates that process variability remains relatively stable, while the process mean is affected by assignable causes (Table 7).

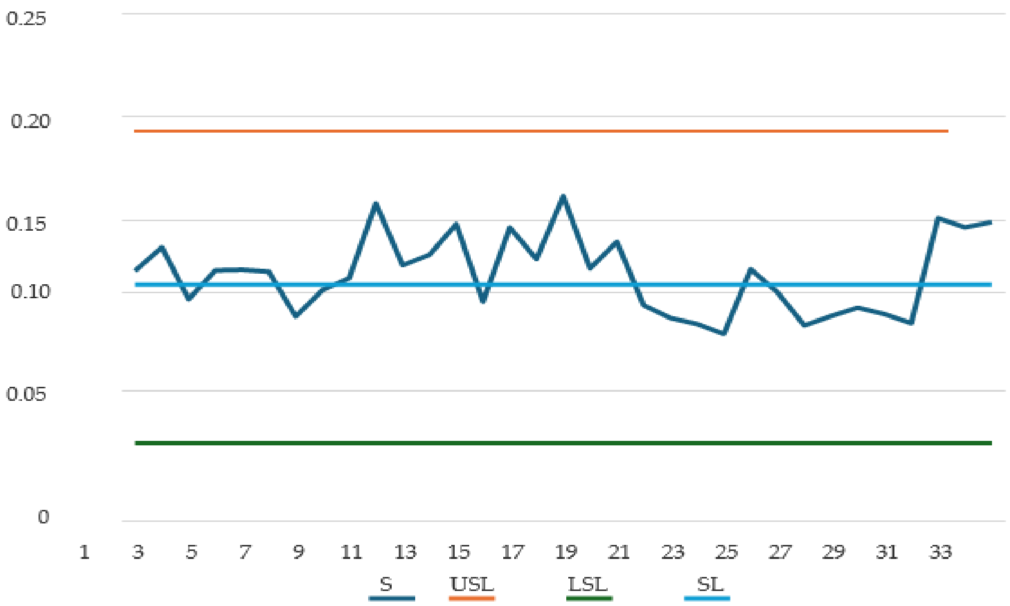

Figure 4. S control chart demonstrating stable process dispersion. Source: Authors' elaboration.

Table 7. Upper and lower control limits for card S.

S		
USL	**LSL**	**SL**
0.191289	0.019498	0.105393

Source: Authors' elaboration.

The R chart (Figure 5) exhibits wider control limits compared to the S chart, reflecting lower sensitivity in detecting variability changes [42] (Table 8).

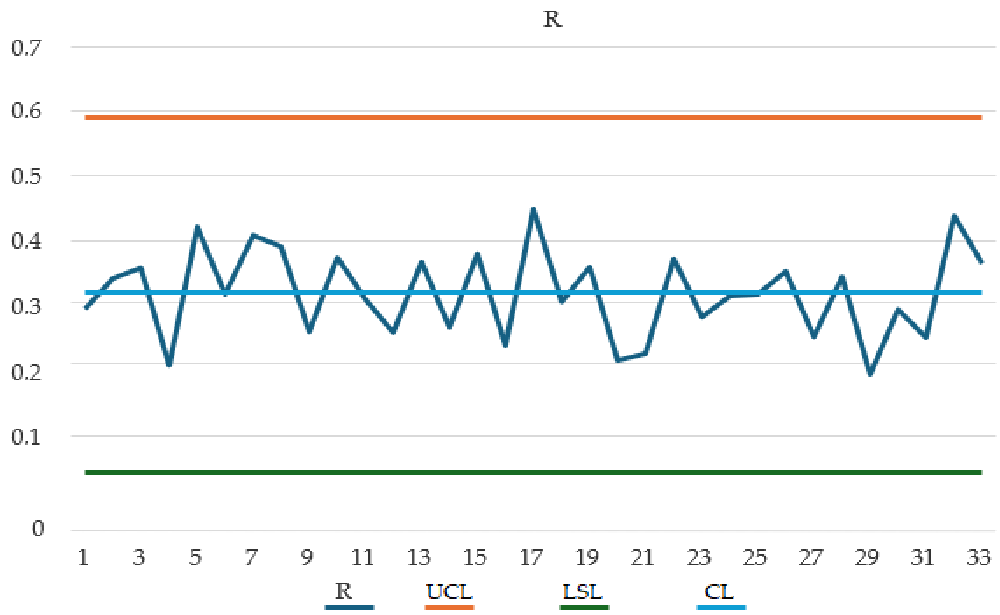

Figure 5. R control chart used for variability range assessment. Source: Authors' elaboration.

Table 8. Upper and lower control limits for chart R.

R		
UCL	**LSL**	**CL**
0.589	0.0429732	0.3159795

Source: Authors' elaboration.

Overall, the SPC analysis indicates that the production operation operates under non-random conditions, requiring further investigation to identify and eliminate sources of instability [41].

In addition to stability assessment, a preliminary process capability analysis was conducted to evaluate the ability of the analyzed process to meet specification requirements. The specification limits for the analyzed characteristic were defined as:

- Upper Specification Limit (USL) = 25.50 mm;
- Lower Specification Limit (LSL) = 24.50 mm.

The estimated process parameters were calculated based on subgroup statistics presented in Table 4. The overall process mean (μ) was determined as the average of subgroup means:

$$\mu = (\Sigma\ X\bar{\text{i}})/\text{k} = 25.0167\ \text{mm} \quad (1)$$

The average subgroup standard deviation was calculated as:

$$S^{-} = 0.1060 \quad (2)$$

Assuming normal distribution of the data, the process standard deviation (σ) was estimated using the c4 correction factor:

$$\sigma = S^{-}/c4 = 0.1060/0.9727 \approx 0.1090\ \text{mm} \quad (3)$$

Based on the estimated parameters, process capability indices were calculated using standard formulas:

$$Cp = (\text{USL} - \text{LSL})/(6\sigma) \quad (4)$$

$$Cpk = \min[(\text{USL} - \mu)/(3\sigma), (\mu - \text{LSL})/(3\sigma)] \quad (5)$$

Substituting the specification limits (USL = 25.50 mm, LSL = 24.50 mm) yields:

$$Cp = (25.50 - 24.50)/(6 \times 0.1090) \approx 1.53 \quad (6)$$

$$Cpk = \min[(25.50 - 25.0167)/(3 \times 0.1090), (25.0167 - 24.50)/(3 \times 0.1090)] \quad (7)$$

$$Cpk \approx \min(1.48, 1.58) = 1.48 \quad (8)$$

Process stability and process capability represent two distinct concepts in statistical quality control. Process stability refers to the absence of assignable-cause variation and is evaluated using SPC charts. In contrast, process capability reflects the ability of a statistically stable process to meet specification requirements. Consequently, capability indices calculated for unstable processes should be interpreted with caution, as they represent potential short-term capability rather than reliable long-term process performance.

The obtained results indicate that the process is capable (Cp > 1.33; Cpk > 1.33). However, due to the lack of statistical control confirmed by SPC analysis, these indices should be interpreted as potential capability rather than actual long-term performance. The statistical validation confirms that the observed improvements in process capability and defect reduction are statistically significant and not attributable to random variation.

The capability analysis assumes an approximately normal distribution of the manufacturing system data, which is a standard assumption in SPC-based capability evaluation.

Despite this assumption, the lack of statistical control limits the reliability of capability indices as measures of long-term process performance.

This indicates that improvement efforts should primarily focus on restoring process stability before capability can be reliably assessed.

Due to the lack of statistical control observed in the SPC analysis, further investigation focused on identifying the underlying causes of the lack of statistical control.

Fault Tree Analysis (FTA) was selected due to its suitability for identifying hierarchical operational relationships in complex production systems. A Fault Tree Analysis (FTA) was conducted based on the 4M analytical model (Man, Machine, Method, Material), incorporating data from quality inspections and process observations (Tables 9 and 10). Each factor was evaluated in terms of its contribution to defect occurrence and detection effectiveness.

Table 9. Occurrence—Factor Analysis.

Factor	Control Point	Standard	Conforming Data	Non-Conforming Data	Assessment	Remarks	Direct Impact
Material	Supply of aluminum profiles for bumper reinforcement	Compliance with dimensional and chemical composition specifications	98% of batches compliant	2% with dimensional deviations	Minor impact	Possible link with downstream processing errors	No
Man (Operator)	Milling head setup	Setup in accordance with workstation instructions	95% correct settings	5% incorrect tool stroke settings	Direct impact	No additional verification after operator change	Yes
Method	Measurement procedure for characteristic A25	Measurement on CMM according to control plan	Performed according to procedure	Measurements using calipers	Indirect impact	Manual measurements are less accurate	No
Machine	CNC milling machine for bracket machining	Stable operation within tolerance range	96% cycles without disturbance	4%—vibrations and X-axis play	Direct impact	Machine geometry inspection required	Yes

Source: Authors' elaboration.

Table 10. Detection—Factor Analysis.

Factor	Control Point	Standard	Conforming Data	Non-Conforming Data	Assessment	Remarks	Direct Impact
Material	Incoming inspection	Dimensional compliance	Compliant	Non-compliance in 2% of batches	Indirect impact	Extension of incoming inspection scope required	No
Man (Operator)	SPC at workstation	Ongoing result registration	Mostly compliant	Occasional missing records	Indirect impact	Additional training required	No
Method	Trend analysis using $\bar{X}$-S and $\bar{X}$-R charts	Analysis under increasing deviations	Not systematically applied	Exceedances of UTL/LTL observed	Direct impact	Immediate corrective actions required	Yes
Machine	Calibration control of measuring equipment	According to schedule	Mostly compliant	Several delayed cases	Direct impact	Implementation of calibration reminder system required	Yes

Source: Authors' elaboration.

The analysis revealed that the main contributors to operational variability are associated with:

- Operator-related factors, particularly incorrect milling head setup;
- Machine-related issues, including vibrations and axis play;
- Method-related deficiencies, such as delayed responses to SPC signals and inconsistent measurement practices.

Material-related factors were found to have a limited impact on the observed nonconformities.

To further refine the analysis, a structured 5WHY approach was applied (Figure 6), considering three analytical paths: identification of the primary root cause, explanation of delayed detection, and identification of systemic causes.

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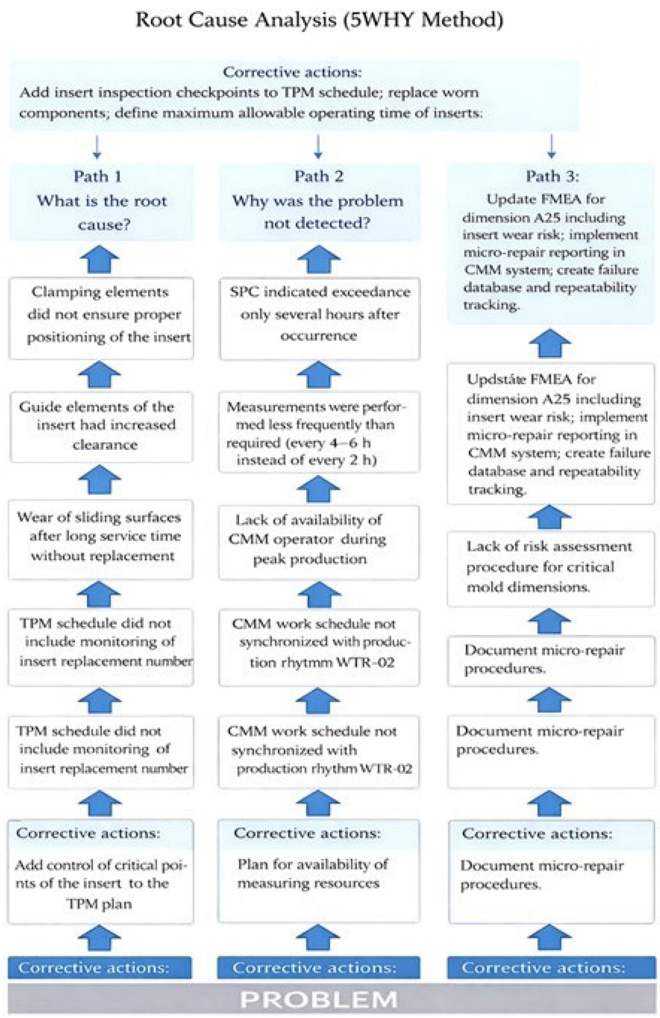

Figure 6. 5WHY analysis. Source: Authors' elaboration.

The results indicate that the primary root cause of the dimensional non-conformity is excessive wear of the mold insert, resulting from insufficient clamping conditions. Additionally, delayed detection of defects was linked to insufficient measurement frequency and limited responsiveness to SPC signals. The systemic analysis revealed broader organizational issues, including [42]:

- Lack of integration of tool wear mechanisms in FMEA;
- Absence of structured maintenance and failure records;
- Insufficient implementation of Total Productive Maintenance (TPM) principles.

These findings were further supported by the Ishikawa diagram (Figure 7), which confirmed the interaction between technical, human, and organizational factors.

Overall, the results demonstrate that lack of statistical control is driven by a combination of technical deficiencies and systemic weaknesses in the Quality Management System, highlighting the need for integrated operational improvements targeting both operational and organizational dimensions.

Furthermore, the findings indicate that achieving process capability without statistical control may lead to misleading conclusions, emphasizing the importance of integrating stability analysis with capability assessment in Lean-oriented quality management.

Pareto–Lorenz analysis was applied to prioritize the dominant sources of nonconformities and identify the process stages with the greatest contribution to defect occurrence (Figure 8), based on the data summarized in Table 11. This tool illustrates the percentage contribution of each defect, starting from the one with the greatest impact on the overall problem. According to the analysis, the factor with the most significant influence on the non-conformity of the final product with expected standards is the final inspection stage, which includes a series of verification activities. The application of Pareto analysis enables the identification and elimination of the primary root cause as a priority, in accordance with the 80/20 principle.

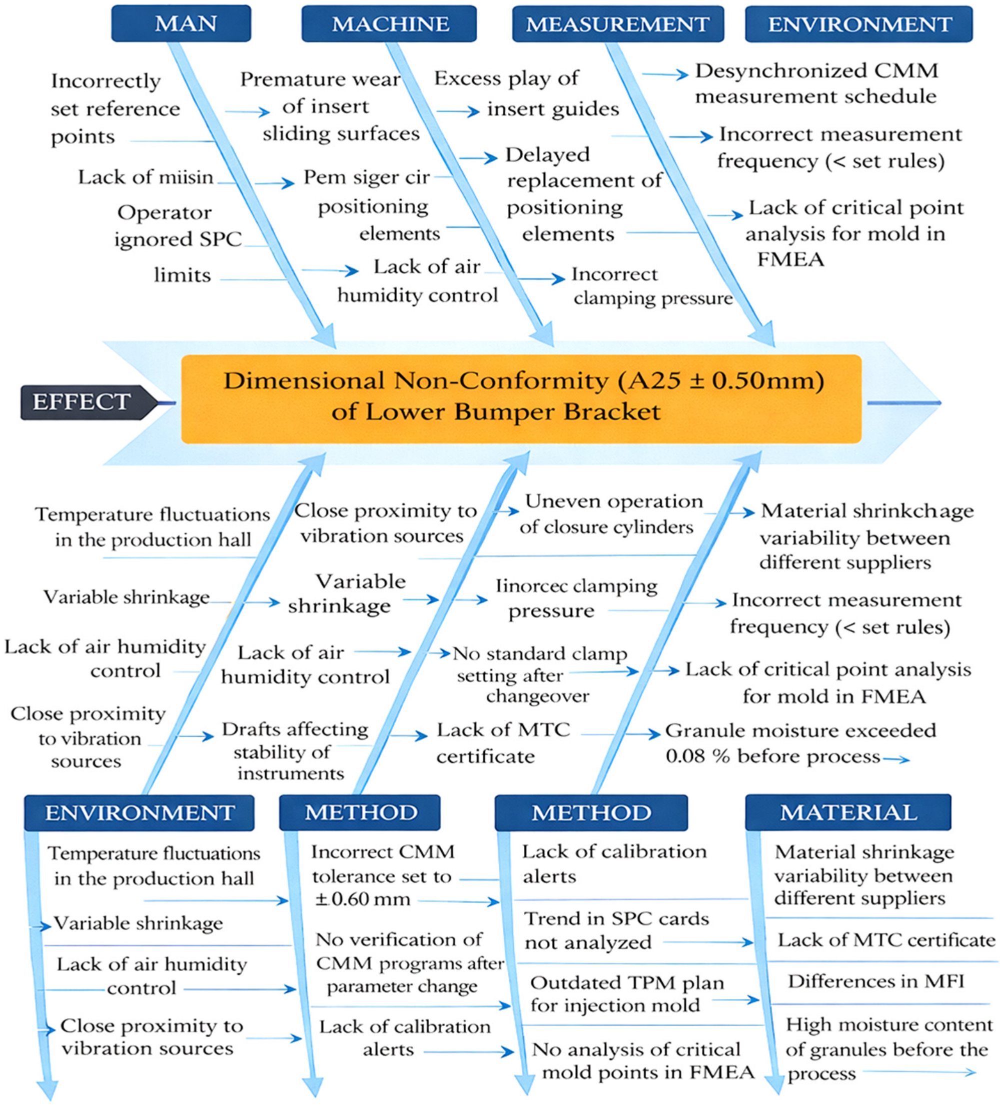

Figure 7. Ishikawa diagram. Source: Authors' elaboration.

The 5W2H method was applied to structure the identified non-conformity and support the definition of corrective actions. The analysis clarified the affected process stage, responsible operational roles, detection mechanism, and potential production impact.

The final stage of the process involved the development of an Action Plan, which translated the results of the preceding analyses into specific measures aimed at eliminating the root causes of the A25 dimensional tolerance deviation. As presented in Table 12, the plan included key actions such as machine parameter calibration and the implementation of a standardized setup, the introduction of in-process inspections conducted every two hours, installation of a temperature sensor equipped with an alarm system, training of WTR-02 line operators, and the implementation of an operator reaction card. Each action was assigned to a responsible individual along with a defined deadline, ensuring effective implementation and minimizing the risk of recurrence, in accordance with the principles of

Lean Management and continuous improvement. This stage represents the final step in problem-solving within the quality management system; therefore, it requires the inclusion of reliable, verified, and clearly defined information, as well as the careful selection of responsible personnel for corrective actions.

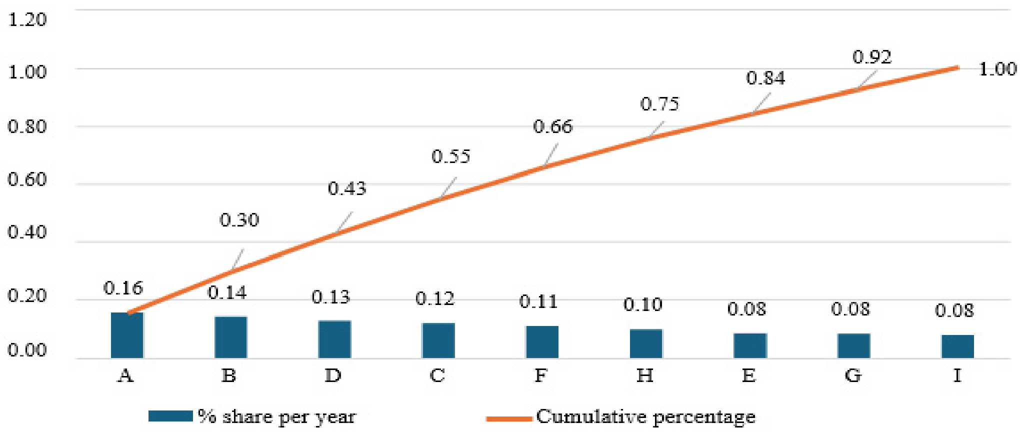

Figure 8. Pareto chart. Source: Authors' elaboration.

Table 11. Annual production data for Pareto–Lorenz analysis.

Process Stage Where Defect Occurred	Number of Defects	Annual Percentage Share, %	Cumulative Percentage, %
A—Final inspection	152	16	16
B—KTL	138	14	30
D—Riveting	124	13	43
C—Aluminum processing	116	12	55
F—Welding	106	11	66
H—Additional assembly	95	10	75
E—Drilling	82	8	84
G—Milling	80	8	92
I—Other	76	8	100

Source: Authors' elaboration.

Table 12. Action Plan for Eliminating the Causes of A25 Dimensional Non-Conformity.

No.	Root Cause	Action	Responsible	Deadline *
1	Incorrect machine parameter settings (pressure and cooling time)	Perform machine parameter calibration and implement a standardized setup sheet	Maintenance Leader	—
2	Lack of in-process control of A25 dimension	Introduce in-process inspection of A25 every 2 h with SPC data recording	Quality Inspector	—
3	Excessive temperature fluctuations in the mold	Install an additional temperature sensor integrated with a visual alarm system	Automation Engineer	—
4	Insufficient operator knowledge regarding machine settings affecting critical dimensions	Conduct training for all WTR-02 line operators on machine settings and customer requirements for A25	Production Manager	—
5	Inadequate documentation of reactions to deviations	Develop and implement an operator reaction card (Reaction Plan) for A25 deviations	Quality Engineer	—

* Deadlines should be defined in accordance with the implementation schedule. Source: own elaboration based on quality improvement analysis.

The developed Action Plan (Table 13) translates the identified root causes into specific corrective and preventive measures. Each action is assigned to responsible personnel, ensuring accountability and supporting effective implementation in line with continuous improvement principles.

Table 13. Process capability indices and ppm before eliminating special events.

ppm	372.84
C*pk*	1.15
C*pu*	1.15
C*pl*	1.24
C*p*	1.20
S	0.14
X⁻	25.02

Source: Authors' elaboration.

The identification of root causes and their linkage to specific process deficiencies provides a structured basis for addressing RQ2. The results support the selection of targeted process improvement approaches, such as standardization, visual management, and preventive control mechanisms, aligned with the identified sources of variability.

5. Discussion

The observed improvements resulted from the combined application of SPC-based analysis, quality management methods, and Lean-oriented operational practices. Rather, the results reflect the combined influence of statistical process control, quality management practices, root cause analysis, process standardization, and selected Lean-oriented operational practices.

While the present study is grounded in conventional SPC-based industrial engineering methods, the identified limitations associated with reactive process monitoring and delayed detection highlight the potential value of future integration with adaptive Industry 4.0 analytical systems. In modern manufacturing environments, machine learning and explainable AI approaches increasingly support predictive anomaly detection, automated clustering, and real-time process adaptation, extending beyond the capabilities of traditional SPC-based monitoring architectures.

Unlike conventional applications, where these tools are often used independently or in an ad hoc manner, the proposed approach operationally links assignable-cause variation, system-level deficiencies, and targeted improvement actions.

The findings support the applicability of integrated operational improvement approaches in manufacturing systems characterized by high process variability. Furthermore, the study extends this analytical framework toward sustainability-oriented interpretation by introducing a quantitative interpretation of defect-related energy losses. This allows for a structured interpretation, which is typically addressed only qualitatively in existing literature.

Overall, the results provide a coherent answer to the research questions. RQ1 is addressed through the identification of systemic QMS gaps, RQ2 through the selection and alignment of process improvement approaches with identified deficiencies, and RQ3 through the evaluation of their impact on process performance and resource-efficiency outcomes.

The findings are consistent with previous studies on process variability reduction and operational improvement practices. This comparative perspective enables a more comprehensive understanding of the implications of an integrated operational approach for process performance and sustainability.

From a theoretical perspective, the study advances existing Lean–QMS research by structuring the analytical relationships between process instability, system-level management deficiencies, and targeted operational interventions. While prior studies typically analyze Lean, QMS, or sustainability separately or through survey-based correlations, the proposed approach introduces a process-oriented analytical sequence linking SPC signals, root cause structures, QMS gaps, and operational improvement practices within a unified industrial framework.

Methodologically, the research integrates qualitative system assessment with SPC-based quantitative evaluation within a case-based industrial research design. This combined analytical structure improves explanatory depth regarding how operational disturbances propagate into quality and resource-efficiency outcomes.

The implementation of these tools (e.g., SMED, Poka-Yoke, standardization) was intended to address the identified sources of variability, resulting in measurable reductions in defect rates and process variability.

The observed improvements resulted from the combined application of Lean-oriented operational practices, quality management methods, SPC-based analysis, and structured root cause investigation.

The environmental and resource-efficiency findings should be interpreted as analytically estimated implications derived from defect reduction rather than as directly measured environmental performance indicators.

The sustainability-oriented contribution should therefore be interpreted as an operational extension of quality management rather than as a complete environmental assessment framework. The study positions defect reduction as a proxy mechanism linking operational instability with additional resource and energy consumption, thereby extending Lean–Green literature toward process-level analytical interpretation.

The analysis revealed that nonconforming products represent a significant source of waste in the studied manufacturing process. Based on both empirical results and theoretical foundations in quality management and Lean Management, a set of improvement tools was proposed and conceptually implemented, including Poka-Yoke, SMED, and Visual Management, supported by root cause analysis methods. The implementation of Poka-Yoke at the final inspection stage addresses the high concentration of detected defects. Redesigning the workstation and simplifying verification using GO/NO-GO gauges reduces operator errors and minimizes the risk of releasing nonconforming products.

These findings are consistent with prior research showing that operational improvement practices contribute to improved process stability and reduced variability [13,14,19]. However, while existing studies primarily focus on operational performance, the present study extends the analysis toward process-level relationships associated with estimated energy-efficiency effects. This indicates that the combined impact of Lean-oriented practices and quality management methods may extend beyond traditional operational quality improvement perspectives.

Additionally, the introduction of Visual Management, supported by real-time monitoring and Andon systems, increased process transparency and responsiveness. The visualization of key quality indicators enables faster detection of deviations, improves communication between production and quality departments, and enhances operator engagement in maintaining process stability.

The "after improvement" results are based on process data obtained after the elimination of identified assignable causes, rather than purely simulated conditions. The study combines empirical process data with analytical modeling, ensuring both practical validity and theoretical interpretability. After eliminating identified disturbances using $\bar{X}$-S control charts, process capability analysis, and quality assessment using the ppm indicator, it was possible to estimate the impact of the improvements on the quality management system. The behavior of the stabilized process is illustrated in Figures 9 and 10.

Post-improvement process performance was evaluated using newly collected production data obtained after implementation of corrective actions under comparable operating conditions.

Specifically, the improvement phase included machine parameter calibration, introduction of in-process inspection, implementation of standardized operating procedures, and operator

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training, as defined in the Action Plan (Table 13). These actions were implemented on the production line and followed by continued operation under standard manufacturing conditions.

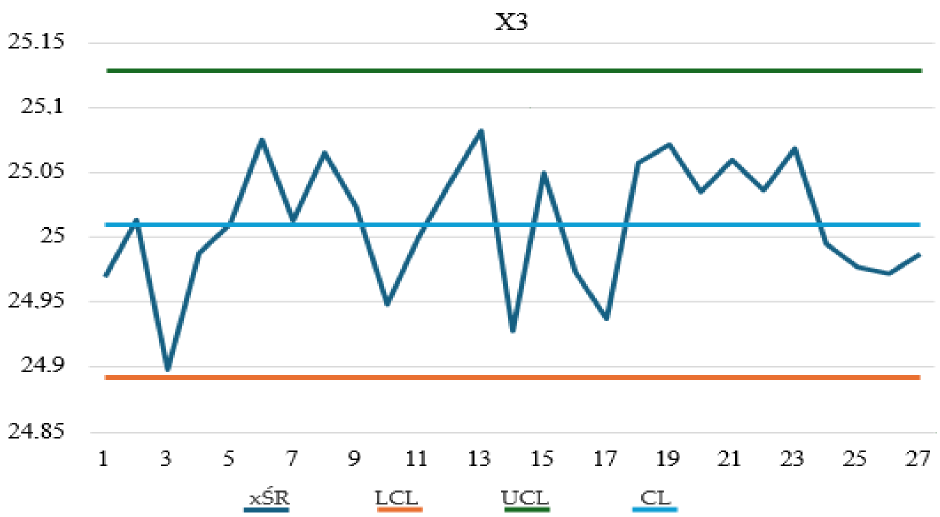

Figure 9. Process flow for X¯3. Source: Authors' elaboration.

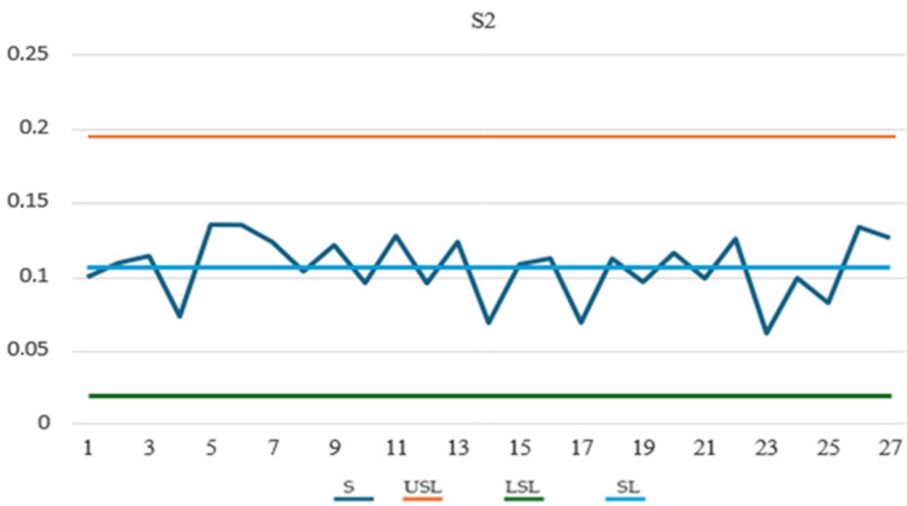

Figure 10. Process flow for S2. Source: Authors' elaboration.

After the implementation of these corrective measures, a new dataset was collected during subsequent production runs using the same measurement system and sampling methodology as in the initial analysis. This enabled a direct before–after comparison under comparable operating conditions.

The post-improvement results, including SPC charts, process capability indices, and the defect rate of 6.72 ppm, are therefore based on empirical observations from the stabilized process. These results reflect actual process performance after intervention rather than a mathematically simulated or idealized scenario.

This approach follows a quasi-experimental before–after design commonly applied in industrial engineering studies.

After eliminating undesirable events, the process can be considered stable. Observed fluctuations result only from natural variability, which is inherent to any production system. Most measurement data exhibit a tolerance buffer, reflected by the distance between specification limits and the mean line (X¯). This effect is particularly evident in the S chart, where only a single measurement exceeded 50% of the permissible dimensional variation.

Process capability indices confirmed the effectiveness of the implemented improvements. Tables 13 and 14 present results for the unstable process, while Tables 15 and 16 show corresponding indicators after process stabilization. For the critical dimension A25 ± 0.50 mm (USL = 25.5 mm; LSL = 24.5 mm), process capability indices exceeded 1.33, confirming compliance with quality requirements [42].

Table 14. PPM indicators for LSL and LCL of the process before eliminating special events.

		z()	p()	ppm
LSL	25.5	3.46	0.00	272.90
LCL	24.5	−3.719181298	9.99348×10^{-5}	99.93
				372.84

Source: Authors' elaboration.

Table 15. Process capability indices and ppm, after eliminating special events.

ppm	6.72
C*pk*	1.48
C*pu*	1.48
C*pl*	1.54
C*p*	1.51
S	0.11
$\bar{X}$	25.01

Source: Authors' elaboration.

Table 16. PPM indicators for the LSL and LCL process after eliminating special events.

		z()	p()	ppm
LSL	25.5	4.43	0.00	4.68
LCL	24.5	−4.60676	2.04×10^{-6}	2.04
				6.72

Source: Authors' elaboration.

Furthermore, the ppm indicator decreased significantly, from 372.84 to 6.72 nonconforming units per million produced parts, corresponding to a 98.20% reduction in nonconformities annually. These results indicate that the combined implementation of Lean-oriented practices, SPC-based analysis, and quality management methods contributed to substantial reductions in process variability and defect rates. From a sustainability perspective, the reduction in nonconforming products can be interpreted as a decrease in resource and energy consumption associated with rework and scrap. Reductions in defects and process variability are associated with improved material and energy performance and lower environmental impact, as waste elimination directly reduces material and energy consumption [3,6,15]. Assuming that each nonconforming unit requires additional processing or replacement, the observed reduction from 372.84 ppm to 6.72 ppm suggests a substantial decrease in energy use per effective unit produced.

The analytical relationship is supported by comparative process performance indicators. The reduction in defect rate from 372.84 ppm to 6.72 ppm, together with the improvement in process capability (Cpk from 1.15 to 1.48), supports the interpretation that the implemented operational improvement interventions contributed to reducing identified sources of variability.

The relationship between defect reduction and energy consumption is based on the empirical observation that each nonconforming unit requires additional processing, rework, or replacement, which generates additional energy demand. Therefore, the defect rate can be interpreted as a proxy variable for quality-related energy losses.

Although direct energy measurements were not available, the proposed approach provides a structured analytical basis for linking quality performance with estimated energy efficiency. By isolating the energy contribution of defective units, the model enables a quantifiable estimation of quality-driven energy losses, which are often overlooked in traditional analyses.

The obtained results support the formulated Research Propositions. The presence of control chart violations confirms process instability (RP1), which was linked to identified QMS deficiencies through root cause analysis.

The implementation of Lean-oriented practices and supporting methods resulted in a measurable improvement in process performance, as evidenced by the increase in Cpk (from 1.15 to 1.48) and the reduction in defect rate from 372.84 ppm to 6.72 ppm (RP2).

Furthermore, the reduction in defect rate corresponds to a decrease in additional energy consumption associated with rework, supporting the relationship between quality improvement and resource efficiency (RP3).

To further interpret the results from an industrial perspective, the impact of defect reduction can be quantified using actual production data.

The reduction in defect rate is calculated as:

$$\Delta\text{ppm} = 372.84 - 6.72 = 366.12\ \text{ppm} \tag{9}$$

Assuming an annual production volume of

$$N = 4{,}500{,}000\ \text{units} \tag{10}$$

the number of avoided defective units can be estimated as:

$$N\_\text{defects\_reduced} = N \times (\Delta\text{ppm}/1{,}000{,}000) \tag{11}$$

$$N\_\text{defects\_reduced} = 4{,}500{,}000 \times (366.12/1{,}000{,}000) \approx 1647\ \text{units/year} \tag{12}$$

This corresponds to approximately 1650 fewer nonconforming components annually under real production conditions.

From an operational perspective, assuming an average rework time of

$$t\_\text{rework} = 5\ \text{min per unit} \tag{13}$$

the total reduction in rework time is:

$$T\_\text{saved} = 1647 \times 5 = 8235\ \text{min} \approx 137\ \text{h/year} \tag{14}$$

From an economic perspective, assuming a conservative cost range of

$$C\_\text{defect} = 10\text{–}50\ \text{EUR per defective unit} \tag{15}$$

the annual cost savings can be estimated as:

$$\text{Cost\_savings} = 1647 \times (10\text{–}50) \approx 16{,}470 - 82{,}350\ \text{EUR/year} \tag{16}$$

These results represent direct and measurable industrial benefits resulting from process stabilization and defect reduction, based on actual production data rather than scenario-based estimation.

To provide a quantitative perspective on sustainability implications, a scenario-based estimation of energy consumption and associated CO_2 emissions was conducted. The analysis considers the additional energy demand generated by defective units requiring rework or replacement, which increases the overall energy intensity of the production process. The total energy consumption of the process can be expressed as:

$$E_{total} = N \cdot E_u \cdot (1 + D \cdot \alpha) \quad (17)$$

where

N—annual production volume [units];

D—defect rate (fraction);

$\boldsymbol{E_u}$—energy consumption per unit [kWh/unit];

α—relative energy consumption of rework.

The energy consumption model is based on the following assumptions, reflecting typical industrial conditions in high-volume manufacturing systems:

- Annual production volume (N = 4,500,000 units): representing large-scale production consistent with the analyzed case.
- Unit energy consumption (Eu = 1.0 kWh/unit): corresponding to the average energy required to produce a single unit under stable operating conditions.
- Defect rate (D): derived from empirical process data (372.84 ppm before improvement and 6.72 ppm after improvement).
- Rework energy factor (α = 1.2): assuming that reprocessing defective units requires approximately 20% more energy than standard production. The adopted value of α is a literature-informed approximation and does not represent a directly measured parameter in the analyzed system.
- Emission factor (EF = 0.75 kg CO_2/kWh): corresponding to the average electricity emission intensity for Poland.

The model assumes that each nonconforming unit generates additional energy demand due to rework, replacement, or additional processing. Therefore, the defect rate is treated as a proxy variable for quality-related energy losses.

This approach enables the isolation of the impact of process inefficiencies on total energy consumption, providing a direct analytical linkage between quality performance and manufacturing efficiency.

To provide a quantitative interpretation of the environmental implications of process improvement, a scenario-based energy estimation model was developed. The model links empirically observed defect reduction with additional energy demand associated with rework and nonconforming units.

The parameter α represents the relative increase in energy consumption associated with reprocessing defective units. In manufacturing systems, rework typically requires additional operations such as re-machining, repeated handling, transport, and inspection, resulting in higher energy demand compared to standard production.

Based on industrial energy studies, rework operations may increase energy consumption by approximately 10–30% depending on process complexity and production technology. For example, studies on manufacturing energy efficiency and process rework indicate that additional processing steps can significantly increase energy intensity at the unit level [43,44]. Therefore, a conservative value of α = 1.2 was adopted, representing a 20% increase in energy consumption for reworked units. All intermediate calculations were performed using full numerical precision. Final values are rounded to the nearest whole kWh for reporting purposes.

The adopted parameters are as follows:

$$N = 4{,}500{,}000 \text{ units/year} \quad (18)$$

$$Eu = 1.0\ \text{kWh/unit} \tag{19}$$

$$\alpha = 1.2 \tag{20}$$

$$D_{\_before} = 372.84\ \text{ppm} = 0.00037284 \tag{21}$$

$$D_{\_after} = 6.72\ \text{ppm} = 0.00000672 \tag{22}$$

The estimated total energy consumption before process improvement is:

$$E_{\_before} = 4{,}500{,}000 \times 1.0 \times (1 + 0.00037284 \times 1.2) \tag{23}$$

$$E\_before \approx 4{,}501{,}007\ \text{kWh} \tag{24}$$

After process stabilization:

$$E_{\_after} = 4{,}500{,}000 \times 1.0 \times (1 + 0.00000672 \times 1.2) \tag{25}$$

$$E_{\_after} \approx 4{,}500{,}018\ \text{kWh} \tag{26}$$

The resulting annual energy savings are:

$$\Delta \text{E} = E_{\_before} - E_{\_after} \approx 990\ \text{kWh/year} \tag{27}$$

CO_2 emissions were estimated using an emission factor:

$$EF = 0.75\ \text{kg}\ \text{CO}_2/\text{kWh (typical for Poland)} \tag{28}$$

$$CO_{2\_before} = 4{,}501{,}007 \times 0.75 \approx 3{,}375{,}756\ \text{kg}\ \text{CO}_2 \tag{29}$$

$$CO_{2\_after} = 4{,}500{,}018 \times 0.75 \approx 3{,}375{,}014\ \text{kg}\ \text{CO}_2 \tag{30}$$

$$\Delta CO_2 \approx 742\ \text{kg}\ \text{CO}_2/\text{year} \tag{31}$$

It should be emphasized that the defect rate used in the model is derived from actual industrial data, while the energy calculation represents an analytical estimation of quality-related energy losses. The adopted value of α is based on literature-informed assumptions and reflects typical industrial conditions rather than a directly measured parameter.

Therefore, the energy and CO_2 results should be interpreted as indicative estimates that illustrate the analytical relationship between defect reduction and environmental impact, rather than precise measurements. Future research should incorporate direct energy monitoring systems to validate and refine the analytical approach.

It is important to emphasize that the reported energy savings are not based on direct measurements but on a model-based estimation. While the reduction in defect rate is derived from actual process data, the corresponding energy and CO_2 values represent an analytical interpretation of quality-related energy losses. Therefore, these results should be understood as indicative rather than exact quantitative values.

Future research should incorporate direct energy measurements and real-time monitoring systems to validate and refine the proposed estimation model.

This study complements existing literature by providing an operational and data-driven perspective on relationships that are often discussed only conceptually.

While the above results represent directly measured industrial improvements, the following energy analysis is based on a scenario-driven estimation model derived from the observed defect reduction.

Although the absolute savings represent a relatively small share of total consumption, they are directly attributable to the elimination of quality-related inefficiencies. From a broader perspective, these findings confirm that process stabilization through Lean–QMS integration contributes not only to improved product quality but also to reduced energy intensity and lower CO_2 emissions, particularly in high-volume manufacturing systems. The comparative results are summarized in Table 17.

Table 17. Energy and CO_2 performance comparison.

Parameter	Before	After	Reduction
Total energy (kWh)	4,501,007	4,500,018	−990
Additional energy losses (kWh)	1007.70	18.1	−989.6
CO_2 emissions (kg)	3,375,756	3,375,014	−742
Defect rate (ppm)	372.84	6.72	−98.2%

Source: Authors' elaboration.

The presented results are based on a comparative analysis of process performance before and after the implementation of Lean interventions, using real production data collected under standard operating conditions.

The calculated Cp and Cpk values are consistent with the SPC analysis, indicating that while the process demonstrates capability, it lacks full statistical stability. This observation aligns with previous studies showing that defect reduction and process stabilization are closely linked to improved operational efficiency.

Despite these limitations, the consistency between SPC results, capability indices, and observed defect reduction supports the internal validity of the findings.

These results are partially aligned with studies that associate Lean practices with improved sustainability-related estimation [3,6,15]. However, unlike many prior works that rely on conceptual or survey-based approaches, this study provides a process-level and data-driven perspective. The findings suggest that the relationship between Lean and sustainability is not only indirect but can be explicitly quantified through quality-related performance indicators.

A summary of the key effects of Lean Management tools implementation in the analyzed enterprise is presented in Table 18, which highlights improvements in process quality, reduction in nonconforming products, and increased production stability.

Table 18. Potential effects of implementing Lean Management tools.

Type of Effect	Description	Expected Outcome
Quantitative Effects	Reduction in nonconforming products	Significant decrease in the annual number of nonconforming products; reduction in financial losses related to complaints
	Reduction in process variability	Compliance with customer requirements
	Shortened response time to deviations	Reduced the time from defect detection to implementation of corrective actions
	Increased inspection efficiency	Higher frequency of in-process inspections with the same time input due to standardized work
	Reduced machine setup time	Minimization of production downtime
Qualitative Effects	Improved employee awareness	Increased staff engagement in preventive quality activities
	Improved interdepartmental communication	Faster information flow and more efficient communication
	Standardization of procedures and simplification of quality documentation	Clear guidelines for operators in case of deviations
	Fostering a culture of continuous improvement	Greater employee initiative in proposing improvement actions
	Increased customer trust	Lower risk of complaints and improved results in quality audits

Source: Authors' elaboration.

The results indicate that the integrated application of improvement interventions combined with root cause analysis effectively reduces process variability and enhances stability. From a sustainability perspective, this contributes to more efficient resource use, reduced material losses, and improved operational performance. Future research should incorporate quantitative environmental indicators such as energy consumption, material waste, or CO_2 emissions to strengthen the sustainability dimension of the analysis. However, existing studies also emphasize that the impact of Lean on sustainability is often indirect and context-dependent, which highlights the importance of linking operational improvements with measurable environmental indicators [3,15].

At the same time, the results support the view that the effectiveness of Lean in achieving sustainability-related implications depends on system-level integration. This is consistent with studies indicating that Lean alone does not guarantee estimated environmental implications or estimated energy savings unless it is aligned with broader management systems and strategic objectives [3,15,22]. Therefore, the observed improvements should be interpreted as the result of integrated Lean–QMS implementation rather than isolated Lean practices.

However, maintaining these results requires continuous process monitoring, adherence to standards, and organizational commitment to continuous improvement. Without these elements, the long-term effectiveness of the implemented solutions may be limited.

In conclusion, the application of Lean Management tools in the studied enterprise demonstrates strong potential for improving process quality and supporting sustainable manufacturing objectives. Although the study demonstrates the potential of Lean and QMS integration to improve process efficiency, its sustainability dimension remains primarily qualitative. In particular, future research should incorporate measurable environmental indicators such as energy consumption, material waste reduction, and CO_2 emissions. The inclusion of such metrics would allow for a more comprehensive evaluation of sustainability performance and strengthen the practical relevance of the proposed approach.

The observed improvements represent measurable industrial benefits achieved under real production conditions. The reduction in defect rate from 372.84 ppm to 6.72 ppm corresponds to a decrease of approximately 366 nonconforming units per million produced parts.

The observed improvements represent measurable industrial benefits achieved under real production conditions. The reduction in defect rate from 372.84 ppm to 6.72 ppm corresponds to a decrease of approximately 366 defective units per million produced parts.

For an annual production volume of 4,500,000 units, this translates into approximately 1650 fewer nonconforming components per year. This reduction directly decreases scrap, rework, and production disturbances.

From an economic perspective, assuming a conservative cost of 10–50 EUR per defective unit, the annual cost savings can be estimated in the range of 16,000 to 82,000 EUR. In addition, assuming an average rework time of 5 min per unit, the reduction corresponds to approximately 137 h of avoided rework operations annually.

These results confirm that the identified improvements provide direct and measurable industrial benefits beyond analytical or scenario-based estimations.

Considering an annual production volume of 4,500,000 units, this reduction translates into approximately 1650 fewer defective components per year. This directly reduces rework, scrap, production disruptions, and quality-related costs.

In addition, the improvement in process capability (Cpk from 1.15 to 1.48) indicates a substantial increase in process robustness and compliance with customer requirements. The reduction in process variability, confirmed by statistical testing ($p < 0.05$), further demonstrates the effectiveness of the implemented improvements under real industrial conditions.

These results directly address RQ3 by demonstrating that the implementation of Lean-oriented practices and supporting methods leads to measurable improvements in process performance, including reduced variability and defect rates, as well as enhanced resource efficiency reflected in lower energy consumption and associated emissions.

In contrast to the dominant body of literature based on survey methods and perceptual data, this study adopts a process-oriented and data-driven approach. This enables the identification of operational relationships between assignable-cause variation, system-level deficiencies, and performance outcomes.

Lean practices contribute to both operational and sustainability-related estimation; however, the strength of this relationship depends on system-level integration and sustainability-oriented implementation [43–46]. There is a growing need for data-driven and process-level analyses to better understand the analytical relationship between Lean and sustainability-related implications [47–51].

The findings demonstrate that reducing process variability and defect rates leads to measurable improvements in reduced resource consumption and sustainability-related estimation, confirming that quality-driven process improvements can enhance sustainability-related implications in high-volume manufacturing systems.

The contribution of this study differs from traditional Lean–Green approaches by introducing a causal and measurable linkage between quality performance and energy efficiency. Instead of treating sustainability as a parallel outcome of Lean-oriented improvement activities, the proposed analytical model demonstrates that defect reduction directly translates into reduced energy consumption and emissions.

This study complements existing literature by providing a data-driven and process-level perspective on relationships that are often discussed only conceptually.

Overall, the findings contribute to the existing body of knowledge by bridging the gap between operational performance and sustainability-related implications through a structured and data-driven analytical model. The study not only confirms previously identified relationships but also extends them by introducing a causal and quantifiable linkage between process quality, system integration, and material and energy performance.

The presented analytical model may serve as a basis for further integration with Industry 4.0 technologies, particularly predictive analytics and explainable AI, enabling a shift toward real-time and proactive process control.

The environmental and resource-efficiency findings should be interpreted with caution. The study does not include direct measurements of energy consumption, monitored sustainability-related interpretation indicators, life-cycle assessment (LCA), or empirical CO_2 emission monitoring. Instead, the environmental analysis is based on a scenario-driven estimation model using defect rates as a proxy for quality-related resource losses. Consequently, the reported sustainability-related effects should be interpreted as analytical estimations supporting managerial decision-making rather than direct empirical validation of estimated environmental implications.

Due to the case study nature of the research, the findings should be interpreted as analytically transferable rather than statistically generalizable.

Although the proposed analytical model was validated within a real industrial environment, its generalizability remains limited by the single-case-study design. Future research should therefore include multi-case industrial validation, direct energy-consumption measurements, and longitudinal assessment of Lean–QMS integration maturity. Further studies may also investigate the integration of digital monitoring systems and Industry 4.0 architectures with the proposed analytical framework.

The findings should therefore be interpreted primarily as an applied industrial demonstration of integrated operational improvement logic within a single manufacturing context.

6. Conclusions

This study examined how Lean-oriented operational practices, QMS-based organizational mechanisms, and SPC-supported process analysis may contribute to process stability, defect reduction, and resource-efficiency performance in a high-volume manufacturing environment. The proposed analytical framework integrated SPC-based process monitoring, QMS gap assessment, root cause analysis, and targeted improvement interventions within a structured industrial evaluation sequence.

The results identified several critical deficiencies in the analyzed Quality Management System, particularly in process monitoring, data integration, operational coordination, and organizational responsiveness. The conducted SPC analysis confirmed the presence of assignable-cause variation and insufficient process stability. Root cause investigation further revealed that operational variability resulted from a combination of technical, organizational, and procedural factors, including inadequate process control, delayed reactions to process deviations, and insufficient standardization of operational practices.

The implementation of targeted improvement measures, including process standardization, enhanced monitoring, visual management, and operator-support mechanisms, contributed to measurable improvements in process performance. After the elimination of identified assignable causes, the process achieved statistical stability and improved capability indicators. The defect rate was reduced from 372.84 ppm to 6.72 ppm, indicating a substantial reduction in process variability and nonconforming products.

From a sustainability perspective, the reduction in defects may also be interpreted as a decrease in quality-related material losses, rework, and energy consumption. Although the environmental analysis was based on a scenario-driven estimation model rather than direct environmental measurements, the findings suggest that operational quality improvements may support more resource-efficient manufacturing performance.

The study contributes to the literature by operationally integrating Lean-oriented practices, SPC-based analytical methods, QMS assessment, and root cause investigation within a unified industrial framework. Unlike many survey-based or conceptual studies, the proposed approach is grounded in empirical production data and process-level industrial analysis. The findings also highlight that Lean-oriented operational practices should be interpreted as complementary components of a broader multidisciplinary improvement system rather than as isolated drivers of process improvement.

At the same time, the study remains limited by its single-case-study design and by the absence of direct real-time environmental monitoring or AI-supported predictive control systems. Future research should therefore focus on validating the proposed framework across multiple industrial sectors and extending the analytical structure toward Industry 4.0-enabled manufacturing environments. In particular, the integration of machine learning, adaptive monitoring systems, automated clustering techniques, and explainable AI may support the transition from reactive SPC-based quality control toward predictive and real-time process management architectures.

Overall, the study demonstrates that integrating SPC-based process analysis, QMS assessment, root cause investigation, and Lean-oriented operational practices may support improved process stability, reduced defect-related losses, and more resource-efficient manufacturing systems.

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