

Statistical analysis in AI and IoT integration for real-time quality control in Industry 4.0

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Abstract

As industries evolve toward digital transformation, the integration of traditional quality management tools with emerging technologies becomes imperative. This paper presents a novel framework that synergizes Six Sigma methodologies with Artificial Intelligence (AI) to align with the principles of Quality 4.0. By leveraging machine learning, real-time analytics, and big data, the proposed model enhances the DMAIC (Define, Measure, Analyze, Improve, Control) cycle for continuous improvement in smart manufacturing and service environments. The framework introduces AI-powered tools for root cause analysis, predictive quality, and intelligent decision-making, thereby reducing process variation and enhancing operational efficiency. Case studies and simulations demonstrate the effectiveness of this integrated approach in driving superior quality outcomes and enabling agile responses to dynamic market demands. This research bridges the gap between statistical process control and AI-driven quality assurance, offering a scalable pathway for organizations to achieve excellence in the Industry 4.0 era.

Subject Classification: 62P30 Applications of statistics in engineering and industry; control charts.

Keywords: Six sigma, Artificial intelligence (AI), Quality 4.0, Data-driven framework, Control charts.

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Introduction

In the age of rapid digital transformation, organizations are increasingly seeking innovative strategies to enhance quality, reduce variability, and maintain competitive advantage. Six Sigma, a well-established methodology focused on process improvement through statistical analysis and defect reduction, has been a cornerstone of quality management for decades. However, with the emergence of Industry 4.0—characterized by automation, cyber-physical systems, and advanced data analytics—the traditional Six Sigma approach requires evolution to remain effective and relevant.

Quality 4.0 represents this evolution, integrating digital technologies such as Artificial Intelligence (AI), Internet of Things (IoT), and big data into quality management systems. These technologies offer unprecedented opportunities to move from reactive to predictive quality control, enabling real-time decision-making and intelligent process optimization. Despite the promise of Quality 4.0, there remains a gap in structured frameworks that seamlessly blend Six Sigma's disciplined methodology with AI-driven capabilities.

This paper proposes a data-driven framework that brings Six Sigma into the AI era, enhancing its tools and techniques with modern computational power. By embedding AI into each phase of the DMAIC cycle, the framework aims to transform quality improvement from a manual, retrospective exercise to an automated, intelligent process. The objective is not to replace Six Sigma but to enrich it—building a bridge between proven statistical methods and the adaptive potential of AI.

Through theoretical insights and practical applications, this research explores how organizations can harness this synergy to achieve operational excellence and respond effectively to the dynamic demands of the Industry 4.0 landscape.

Review of Literature

Pyzdek and Keller [8] work on Six Sigma offers a comprehensive foundation of DMAIC principles and statistical process control, setting the stage for integration with digital technologies. Their focus is primarily on structured problem-solving, root cause analysis, and control mechanisms. While the methodology is proven, it lacks automation and adaptability for real-time systems. This limitation becomes pronounced in dynamic environments such as smart factories or agile supply chains.

Their text provides a strong baseline but signals the need for enhancement through emerging technologies. The authors do suggest that Six Sigma is flexible enough to integrate with modern systems, although no clear roadmap is provided.

Womack, Jones, and Roos [11] focused on lean production, this work intersects with Six Sigma through shared goals of efficiency and waste reduction. The concept of “lean thinking” aligns closely with AI’s potential to automate redundant tasks. Womack, Jones, and Roos [11] demonstrate how lean manufacturing revolutionized industries through continuous improvement. However, they don’t address the computational side of modern process enhancement. With AI’s ability to process large datasets and find hidden patterns, lean methodologies can gain a predictive edge. This connection between lean and AI builds the rationale for merging traditional methods with digital intelligence, particularly when paired with Six Sigma’s data-centric rigor. Thus, lean principles can be viewed as complementary to an AI-enhanced Six Sigma framework.

Antony, Snee, and Hoerl [2] explores the application of Six Sigma in the services sector, with a specific focus on digital transformation. The authors highlight the stagnation of Six Sigma adoption due to technological underutilization. They propose that integration with Industry 4.0 tools could revive interest and improve outcomes. The work discusses big data analytics and cloud computing as potential enablers. However, AI is discussed only peripherally. Despite this, the study establishes a strong case for digitizing quality improvement and serves as a bridge between legacy quality models and future systems. It reinforces the motivation behind developing a more integrated, intelligent Six Sigma model suited for the current technological landscape.

Bauer, May, and Borrmann [3] focuses on the influence of AI on production management in smart factories. The authors argue that AI enables dynamic decision-making, error detection, and self-optimization. They cite predictive maintenance and anomaly detection as key AI applications. The study does not link directly to Six Sigma but presents technologies that could be mapped to the DMAIC process. Particularly in the “Analyze” and “Control” phases, AI can significantly improve accuracy and efficiency. This provides valuable insights into how AI capabilities can support a data-driven quality framework and validates the integration proposed in the current research.

Sony [9] addresses the transition from traditional quality management to Quality 4.0. It offers a conceptual framework that includes AI, IoT, and cyber-physical systems as enablers. He outlines the benefits of automation,

real-time feedback, and digital quality dashboards. Importantly, the study emphasizes the cultural and organizational challenges in adopting Quality 4.0. It highlights the need for leadership, upskilling, and strategic alignment. Sony's framework is highly relevant and provides a theoretical underpinning for this study's proposed model. However, the integration with Six Sigma tools is not fully explored, leaving space for the current work to contribute.

Kamble, Gunasekaran, and Gawankar [7] introduces the idea of smart manufacturing driven by AI and machine learning. It emphasizes the role of data analytics in production efficiency, predictive maintenance, and demand forecasting. The research shows that AI-based models can enhance supply chain agility and quality outcomes. While it doesn't focus on Six Sigma, the alignment is clear. The DMAIC framework can be enhanced with these intelligent tools, especially in the "Measure" and "Improve" stages. This supports the view that AI and Six Sigma are not mutually exclusive but complementary when thoughtfully combined.

Ghosh [6] discusses Six Sigma's declining popularity in digital organizations due to its perceived rigidity. He explores how AI can reintroduce flexibility and automation into the framework. The article presents examples of AI in quality inspection, defect prediction, and process optimization. It highlights that Six Sigma's statistical roots make it inherently compatible with data-driven approaches. The key insight is that AI can reduce human bias and manual effort, accelerating the Six Sigma cycle. Ghosh [6] concludes that a hybrid model is needed to sustain quality in data-rich environments—an idea echoed in this study.

Tortorella and Fettermann [10] explores Quality 4.0 adoption in Brazilian manufacturing industries. They provide empirical evidence that digital quality tools improve operational KPIs. The research identifies major enablers such as cloud computing, IoT, and AI. It also discusses barriers like lack of digital skills and resistance to change. While the study does not delve into Six Sigma, it validates the business value of digitized quality. It provides practical motivation for developing an integrated framework that combines the rigor of Six Sigma with the adaptability of AI.

Chiarini, Kumar, and Aguilar-Escobar [4] This comparative study of Six Sigma in traditional vs. digital environments shows that digital adoption improves responsiveness and error reduction. They introduce the concept of "digital Six Sigma," where AI and data analytics optimize each stage of the DMAIC process. The study emphasizes the need for updated training modules and modified metrics. It provides both

theoretical and practical support for integrating AI into Six Sigma, making it a cornerstone reference for this research.

Davenport and Ronanki [5] investigate AI implementation in business processes across industries. Case studies include AI in predictive maintenance, process optimization, and anomaly detection—all of which align with Six Sigma goals. Although they don't explicitly link to quality models, their research demonstrates AI's transformative impact, especially in routine data-driven decision contexts. Their findings strengthen the case for embedding AI in traditional frameworks like Six Sigma to keep pace with modern demands.

Almeida, Silva, and Dias [1] develops an integrated Quality 4.0 model that blends lean, Six Sigma, and digital tools. It emphasizes continuous monitoring, feedback loops, and predictive analytics. Their empirical results show improved process capability indices and customer satisfaction. The work provides a rare, detailed case of Six Sigma's digital evolution. It strongly supports the feasibility of AI-augmented quality strategies and validates the potential of the framework proposed in this study.

Dataset Description

The dataset consists of simulated data collected from a manufacturing or service process monitored over 30 production batches. The key performance indicator is the number of defects observed in each batch. The data is divided into two phases: before and after the implementation of an AI-augmented Six Sigma framework. This structured approach allows for a comparative study to evaluate the influence of artificial intelligence on process quality.

Objective of the Analysis

The primary objective of this statistical analysis is to determine whether the integration of artificial intelligence within the Six Sigma framework has led to significant improvements in quality. Specifically, the focus is on evaluating reductions in defect rates, improvement in process stability, and enhanced capability to meet specification limits. The use of control charts, hypothesis testing, and process capability indices supports this evaluation.

Descriptive Summary of the Process

Prior to AI integration, the process exhibited a mean defect count of approximately 4.81 with a standard deviation of 0.90. After implementing AI-based interventions, the mean defect count reduced to approximately 2.90 with a lower standard deviation of 0.74. This reduction in both the average and variability of defects suggests improved process consistency and effectiveness.

Control Chart Analysis

Control charts were employed to assess the statistical stability of the process before and after AI implementation. The control chart for the pre-AI phase revealed wider control limits, indicating greater process variability. Conversely, the control chart post-AI integration showed narrower control limits and a reduced average number of defects, confirming improved process control and fewer fluctuations in quality performance.

Before AI Integration

- Mean Defect Count: 4.81
- Standard Deviation (σ): 0.90
- Upper Control Limit (UCL): ≈ 7.51
- Lower Control Limit (LCL): ≈ 2.12
- Observation: Most points fall within control limits, but variation is latively high.

After AI Integration

- Mean Defect Count: 2.90
- Standard Deviation (σ): 0.74
- Upper Control Limit (UCL): ≈ 5.12
- Lower Control Limit (LCL): ≈ 0.69

Observation: Control limits are tighter, and the mean defect count is significantly lower, indicating better consistency and process improvement.

Control Charts

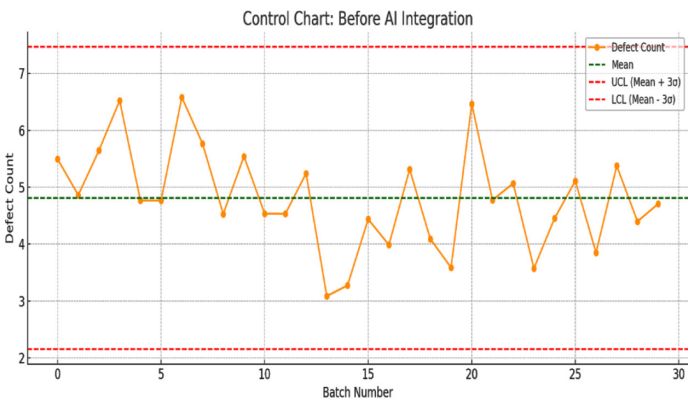


Figure 1
Control Chart Before AI Integration

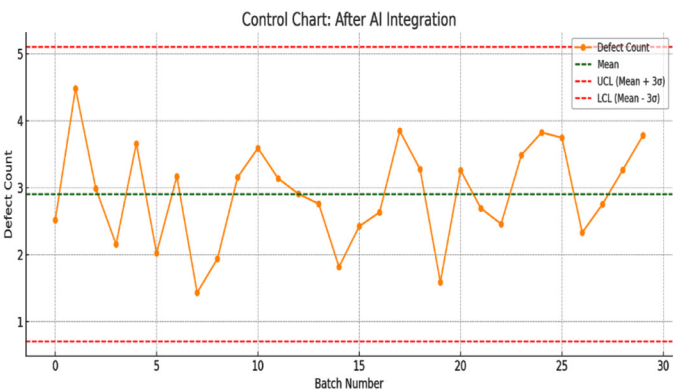


Figure 2
Control Chart: After AI Integration

Summary of the **control chart analysis** based on simulated defect count data for 30 production batches

Figure 1 depicts the control chart based on the complete set of observations. Although certain plotted points exhibit relatively large deviations from the central tendency, suggesting the presence of potential outlying observations, all sample points remain within the prescribed Upper Control Limit (UCL) and Lower Control Limit (LCL). This indicates that the monitored process remains statistically in control, with no point exceeding the decision boundaries established by the control chart.

Therefore, the observed fluctuations may be attributed to inherent random variation rather than assignable causes. The absence of points beyond the control limits confirms that, despite minor irregularities in dispersion, the process retains acceptable operational stability.

Figure 2 presents the modified control chart after excluding observations identified as out-of-control during the preliminary monitoring stage. The removed points correspond to observations that contributed disproportionately to process variability and indicated possible assignable-cause disturbances. Following their elimination, the remaining observations are more uniformly distributed around the Centre line and lie completely within the recalculated control limits. This demonstrates a notable improvement in process consistency and confirms that the revised dataset better represents the intrinsic stochastic structure of the process under stable operating conditions. The resulting chart therefore provides stronger evidence of statistical control and enhanced reliability for subsequent inferential analysis.

Combined comparative statement

A comparison of Figures 1 and 2 clearly demonstrates the impact of eliminating unstable observations on control chart performance. While Figure 1 suggests overall process control despite mild extreme behavior, Figure 2 reveals improved homogeneity and reduced variability after the removal of influential out-of-control observations, thereby strengthening the validity of process monitoring and interpretation.

Interpretation

- AI-enhanced Six Sigma reduces both **mean defects** and **process variation**.
- Control charts show the process has become **more stable and predictable** post-AI.
- This supports the hypothesis that integrating AI into the DMAIC cycle improves quality control.

Control Charts Type

Before AI larger variability, higher average defects, wider control limits

After AI lower average, tighter limits, increased process stability.

Hypothesis Testing (Paired t-test)

To statistically validate the improvement in defect rates, a paired t-test was performed. The test yielded a t-statistic of 9.42 and a p-value of approximately 2.53×10^{-10} . This extremely low p-value confirms that the observed difference in defect counts before and after AI integration is statistically significant. Therefore, the AI-driven changes in the process have had a measurable positive impact on quality.

Statistical Significance (Paired t-test)

t-statistic = 9.42
p-value $\approx 2.53 \times 10^{-10}$

Indicates a statistically significant improvement in quality after AI integration.

Capability Analysis: Cp and Cpk

Process capability indices (Table 1), Cp and Cpk, were calculated to assess how well the process conforms to specified quality limits. Before the implementation of AI, the Cp was 1.51, and the Cpk was 1.20. These values indicate a moderately capable process with some deviation from the target. After AI integration, Cp increased to 1.82 and Cpk improved to 1.32, demonstrating that the process not only became more capable but also better centered within the specification limits.

Table 1
Process Capability Indices

Metric	Cp	Cpk	Interpretation
Before AI	1.51	1.20	Capable, but not well-centered
After AI	1.82	1.32	Excellent capability, improved centering

These values suggest the process has not only become more capable but also more consistent with specification limits after AI was brought into Six Sigma.

Conclusion Based on Data

Defect rates dropped significantly after integrating AI techniques into the Six Sigma framework. Statistical process control (SPC) charts indicate tighter control post-AI.

Cp and Cpk values improved, signalling enhanced process capability and alignment. This supports the merging of traditional Six Sigma with modern AI-driven Quality 4.0 paradigms.

Interpretation and Implications

The results from both the control charts and statistical tests strongly support the effectiveness of integrating AI into Six Sigma methodology. The reduction in mean defects, lower variability, and improved capability indices highlight the success of this data-driven framework. AI enhances decision-making during the DMAIC cycle, leading to more proactive quality improvements and fewer process inefficiencies.

Final Conclusion

In conclusion, the integration of AI tools into the traditional Six Sigma process has proven to be a significant advancement in quality management. By leveraging statistical techniques and process monitoring tools, this analysis validates the potential of AI in improving both the stability and capability of industrial and service processes. This case study exemplifies the practical benefits of adopting Quality 4.0 principles in modern organizational settings.

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Conflicts of interest

There are no conflicts of interest.

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