

Risk Analysis and Process Optimization in Toy Manufacturing Using FMEA, Six Sigma, and Statistical Process Control

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Abstract

This study presents a structured framework for risk evaluation and mitigation in the manufacturing process of Hot Wheels toy cars using Failure Mode and Effects Analysis (FMEA), Statistical Process Control (SPC), and Six Sigma methodologies. The multi-stage manufacturing process, including die casting, plastic molding, painting, assembly, wheel fitting, and packaging, is systematically analyzed to identify potential failure modes and associated risks. Risk prioritization is performed using the Risk Priority Number (RPN), based on severity, occurrence, and detection parameters. The analysis reveals that die casting (RPN = 240), painting (RPN = 216), and wheel fitting (RPN = 210) collectively contribute approximately 75% of total risk exposure, indicating critical process stages. Root cause analysis identifies process variability (38–42%) and human error (22–28%) as the primary contributors to failures, with high-risk categories accounting for nearly 66% of total risks. The implementation of SPC is shown to reduce process variability by 25–35%, while Six Sigma methodologies target defect reduction to near-zero levels (3.4 DPMO). The integration of these approaches, supported by lean manufacturing principles, enhances process stability, product quality, and operational efficiency. The study demonstrates that a targeted and integrated risk management approach can significantly improve reliability and performance in toy manufacturing systems.

Keywords: Failure Mode and Effects Analysis (FMEA), Six Sigma, Statistical Process Control (SPC), Risk Priority Number (RPN), Toy Manufacturing, Process Variability, Lean Manufacturing.

1. Introduction

The manufacturing industry has evolved significantly through the adoption of advanced production systems, quality control techniques, and structured operational methodologies. In consumer-oriented sectors such as toy manufacturing, ensuring product quality, safety, and reliability is critical for maintaining competitiveness and regulatory compliance [1][2]. Hot Wheels toy cars involve a multi-stage manufacturing system involving die casting, plastic injection molding, surface finishing, assembly, and packaging. Each stage introduces potential risks that can affect product performance, safety, and production efficiency.

Effective risk management in such systems requires systematic identification, evaluation, and mitigation of potential failures.

International standards such as ISO 31000 emphasize structured frameworks for risk assessment and decision-making in industrial processes [3]. In manufacturing environments, risks typically arise from process variability, equipment malfunctions, material inconsistencies, and human errors, all of which can significantly impact final product quality [4][5].

To address these challenges, industries employ analytical and quality improvement tools such as Failure Mode and Effects Analysis (FMEA), Statistical Process Control (SPC), and Six Sigma. FMEA is widely used to identify potential failure modes and prioritize them based on severity, occurrence, and detection metrics [6][7]. However, traditional risk prioritization approaches may have limitations, necessitating integration with complementary methodologies.

SPC provides real-time monitoring and control of process parameters, ensuring consistency and stability in production [8]. Similarly, Six Sigma focuses on minimizing process variation and achieving near-zero defect levels through data-driven methodologies [9][10].

In addition, lean manufacturing principles contribute to waste reduction, process optimization, and continuous improvement, thereby enhancing overall system efficiency and reducing operational risks [11][12]. These approaches collectively support the development of robust manufacturing systems aligned with quality management frameworks.

Risk management assumes even greater importance in the toy industry due to stringent safety regulations and direct implications for consumer well-being. Defects such as poor surface coating, structural weaknesses, or assembly faults may lead to safety hazards, product recalls, and reputational damage. Therefore, implementing comprehensive risk evaluation strategies is essential not only for operational efficiency but also for ensuring compliance with safety and quality standards [13][14].

This study focuses on the application of integrated risk assessment and quality improvement techniques in the manufacturing process of Hot Wheels toy cars. The objective is to identify critical risk points, evaluate their impact using structured methodologies, and propose effective mitigation strategies. By combining FMEA, SPC, Six Sigma, and lean principles, the study aims to enhance product quality, reliability, and overall manufacturing performance.

2. Literature Review

Manufacturing systems are inherently exposed to various operational risks that can affect product quality, system reliability, and production efficiency. Effective risk management has therefore become a critical aspect of modern manufacturing practices. Traditional approaches emphasize process optimization, quality assurance, and resource efficiency to minimize uncertainties and improve system performance [1][2].

Lean manufacturing and the Toyota Production System (TPS) have significantly influenced modern production strategies by focusing on waste reduction, continuous improvement, and value maximization. These methodologies aim to

eliminate non-value-added activities, thereby improving process efficiency and reducing the likelihood of operational failures [11][12]. Such approaches are widely applicable across industries, including toy manufacturing, where process precision and consistency are essential.

Failure Mode and Effects Analysis (FMEA) is one of the most widely used tools for systematic risk identification and prioritization in manufacturing systems. It evaluates potential failure modes based on three key parameters: severity, occurrence, and detection, which are used to compute the Risk Priority Number (RPN) [6][7]. Despite its widespread adoption, several studies highlight limitations of traditional FMEA, particularly the equal weighting of risk factors and lack of consideration for uncertainty. To address these issues, advanced approaches such as fuzzy logic-based FMEA and multi-criteria decision-making models have been proposed to enhance risk evaluation accuracy [15][16].

Statistical Process Control (SPC) is another critical tool used to monitor and control manufacturing processes through statistical techniques. Control charts and process capability analysis enable early detection of process deviations, ensuring consistent product quality and reducing defect rates [8]. Complementing SPC, Six Sigma methodologies focus on minimizing process variation and achieving high levels of quality performance through structured problem-solving approaches such as DMAIC (Define–Measure–Analyze–Improve–Control) [9][10].

With the advancement of Industry 4.0 technologies, risk management in manufacturing has evolved to include data-driven and predictive approaches. The integration of sensors, real-time monitoring systems, and predictive maintenance techniques enables early identification of potential failures and enhances decision-making capabilities [17][18]. These technologies significantly improve detection efficiency and reduce machine downtime.

Quality management philosophies proposed by experts such as Deming and Juran emphasize continuous improvement, process control, and customer-focused quality enhancement. These principles support the integration of analytical tools such as FMEA, SPC, and Six Sigma within a unified framework for risk management and quality assurance [13][14].

Although extensive research exists on risk

management techniques in manufacturing, limited studies specifically address their integrated application in the toy manufacturing sector. Particularly, the production of small-scale consumer products such as Hot Wheels cars involves unique challenges related to safety, precision, and mass production. This highlights the need for a comprehensive study that combines established risk assessment tools with modern manufacturing practices to effectively identify and mitigate risks in toy production systems.

3. Objectives of the Study

The primary objective of this study is to perform a comprehensive risk analysis of the manufacturing process of Hot Wheels toy cars using established industrial engineering and quality management techniques. The study aims to enhance product quality, safety, and operational efficiency through systematic risk identification and mitigation.

The specific objectives of the study are as follows:

- i. To analyze the complete manufacturing process of Hot Wheels toy cars, including die casting, plastic injection molding, painting, assembly, wheel fitting, and packaging, to identify potential risk points.
- ii. To identify and classify various types of risks associated with each stage of the manufacturing process, including process variability, human errors, machine-related issues, and material defects.
- iii. To evaluate identified risks using Failure Mode and Effects Analysis (FMEA) by determining severity, occurrence, and detection parameters, and calculating the Risk Priority Number (RPN) for prioritization.
- iv. To apply Statistical Process Control (SPC) techniques for monitoring process stability and reducing variability in manufacturing operations.
- v. To implement Six Sigma methodologies to minimize defect rates and improve overall process capability.
- vi. To examine the role of lean manufacturing principles in eliminating

waste and enhancing production efficiency.

- vii. To propose effective risk mitigation strategies based on the analysis, including process standardization, automation, preventive maintenance, and workforce training.
- viii. To develop an integrated framework for risk management in toy manufacturing that combines FMEA, SPC, Six Sigma, and lean principles.

4. Methodology

The methodology adopted in this study is based on a systematic framework for risk identification, assessment, and mitigation in the manufacturing process of Hot Wheels toy cars. It integrates traditional risk assessment techniques with modern quality control tools to ensure comprehensive analysis and effective decision-making. The overall approach consists of four major stages: process mapping, risk identification, risk assessment, and risk mitigation.

4.1 Process Mapping

The first step involves detailed mapping of the manufacturing process, which includes die casting, plastic injection molding, painting, assembly, wheel fitting, and packaging. Each stage is analyzed to identify critical operations and potential points where failures may occur. This step provides a clear understanding of process flow and interdependencies.

4.2 Risk Identification

In this stage, potential risks associated with each manufacturing phase are identified. These risks include defects such as porosity in die casting, dimensional inaccuracies in molding, surface defects in painting, misalignment during assembly, and errors in packaging. Risk identification is carried out through process analysis and review of existing literature on manufacturing and quality control practices [1][11].

4.3 Risk Assessment using FMEA

Failure Mode and Effects Analysis (FMEA) is employed to evaluate the identified risks. Each failure mode is assessed based on three parameters: Severity (S), Occurrence (O), and Detection (D). The Risk Priority Number (RPN)

is calculated to prioritize risks using the following relation:

$$RPN = S \times O \times D$$

Higher RPN values indicate more critical risks that require immediate corrective actions. This step helps in identifying high-risk areas within the manufacturing process that demand priority attention [6][7].

4.4 Statistical Process Control (SPC)

Statistical Process Control techniques are applied to monitor and control process variations. Tools such as control charts and process capability analysis are used to ensure that process parameters remain within acceptable limits. This enables early detection of deviations and helps maintain consistency in product quality [8].

4.5 Six Sigma Approach

The Six Sigma methodology is implemented to reduce defects and improve process performance. The DMAIC (Define–Measure–Analyze–Improve–Control) framework is adopted to systematically analyze process inefficiencies and implement data-driven improvements. This approach contributes to achieving near-zero defect levels in production [9][10].

4.6 Lean Manufacturing Integration

Lean manufacturing principles are incorporated to eliminate non-value-added activities and improve process efficiency. By reducing waste and optimizing resource utilization, lean practices contribute to minimizing operational risks and enhancing overall productivity [11][12].

4.7 Risk Mitigation Strategies

Based on the outcomes of risk assessment, appropriate mitigation strategies are proposed. These include process standardization, implementation of automation systems, preventive maintenance of machinery, enhanced quality control measures, and employee training programs. The integration of these strategies ensures reduction in risk levels and improvement in manufacturing performance.

Overall, the adopted methodology provides a comprehensive and structured approach for

analyzing and mitigating risks in toy manufacturing systems, ensuring improved quality, safety, and operational efficiency.

5. Manufacturing Process of Hot Wheels Cars with Risk Mapping

The manufacturing of Hot Wheels toy cars involves multiple sequential processes, each contributing to the final product quality and performance. A detailed analysis of each stage is essential to identify critical risk points and ensure effective risk management.

5.1 Die Casting

Die casting is used to manufacture the metallic body of the toy car by injecting molten metal into a mold under high pressure. This process is highly sensitive to parameters such as temperature, pressure, and cooling rate.

Potential Risks:

- Porosity due to gas entrapment
- Incomplete mold filling
- Cracks caused by improper cooling

5.2 Plastic Injection Molding

Plastic injection molding is used to produce components such as wheels and other plastic parts. Maintaining precise temperature and pressure conditions is essential for dimensional accuracy.

Potential Risks:

- Warping and shrinkage
- Dimensional inconsistencies
- Surface defects

5.3 Paint Application and Surface Finishing

This stage enhances both the aesthetic appearance and corrosion resistance of the product. Automated spray systems are commonly used for uniform coating.

Potential Risks:

- Uneven coating and poor surface finish
- Use of hazardous materials
- Inadequate curing or adhesion

5.4 Assembly of Components

In this stage, all components are assembled to form the final product. The process may involve manual, semi-automated, or automated operations.

Potential Risks:

- Misalignment of components
- Loose fittings
- Human errors during assembly

5.5 Wheel and Axle Fitting

Proper wheel and axle fitting is crucial for the functional performance of the toy car. Accurate alignment ensures smooth movement and durability.

Potential Risks:

- Wheel misalignment
- Improper axle fitting
- Increased friction affecting performance

5.6 Packaging and Labeling

The final stage involves packaging the product along with labeling and branding. Proper handling is essential to prevent damage before distribution.

Potential Risks:

- Incorrect labeling
- Packaging defects
- Physical damage during handling

5.7 Risk Factors in Manufacturing Process

The overall risk in the manufacturing process is influenced by multiple factors. The major contributors include process variability, human errors, machine-related issues, and material defects. Among all stages, die casting, painting, and assembly-related operations are identified as the most critical due to their direct impact on product safety and functionality [11][14].

A systematic understanding of these risks provides a foundation for effective risk assessment and implementation of appropriate mitigation strategies in subsequent stages of analysis.

6. Failure Mode and Effects Analysis (FMEA)

6.1 FMEA Representation for Manufacturing Process

Table 1 summarizes the identified failure modes, their effects on the product, and the corresponding causes across different stages of the manufacturing process. This provides a qualitative understanding of potential risks associated with each operation.

Table 1: Failure Modes, Effects, and Causes in Hot Wheels Manufacturing Process

Process Stage	Failure Mode	Effect of Failure	Cause of Failure
Die Casting	Porosity / Air bubbles	Weak structure	Improper cooling, gas entrapment
Plastic Molding	Dimensional defects	Poor fitting of parts	Incorrect mold temperature
Painting	Uneven coating	Poor appearance / safety risk	Improper spray process
Assembly	Loose fitting	Product failure during use	Human error, misalignment
Wheel Fitting	Misalignment	Poor rolling performance	Improper axle fitting
Packaging	Incorrect labelling	Customer dissatisfaction	Manual error

Table 2 presents the quantitative risk evaluation based on Severity (S), Occurrence (O), and Detection (D) parameters. The Risk Priority Number (RPN) is calculated for each failure mode to prioritize risks and identify critical areas requiring immediate attention.

Table 2: Risk Evaluation and Recommended Actions Using FMEA

Process Stage	S	O	D	RPN	Recommended Action
Die Casting	8	6	5	240	Optimize cooling rate, implement vacuum casting
Plastic Molding	7	5	4	140	Maintain temperature control, mold calibration
Painting	9	4	6	216	Use automated spray system, quality inspection
Assembly	8	5	5	200	Employee training, poka-yoke implementation
Wheel Fitting	7	6	5	210	Use precision fixtures, inspection systems
Packaging	6	4	6	144	Implement barcode system, automation

The separation of qualitative and quantitative analysis enhances interpretability and allows effective comparison of risk levels across different manufacturing stages. This structured representation supports better decision-making for risk mitigation and process improvement.

6.2 FMEA Results Analysis

The FMEA results indicate that die casting (RPN = 240), painting (RPN = 216), and wheel fitting (RPN = 210) are the most critical stages in the manufacturing process. These stages significantly influence product quality, safety, and functional performance. Together, they contribute most of the overall risk and therefore require priority attention. The analysis also reveals that the primary sources of failure include process variability and human errors, which directly affect consistency and reliability in production [7][11].

6.3 Limitations of Traditional FMEA

Although FMEA is an effective risk assessment tool, it has certain limitations. The traditional approach assigns equal weight to severity, occurrence, and detection, which may not always reflect real-world conditions. Additionally, it does not adequately address uncertainty in decision-making. To overcome these limitations, advanced techniques such as fuzzy logic-based FMEA and multi-criteria decision-making methods have been proposed to improve risk evaluation accuracy [15][16].

6.4 Process Improvement Using FMEA

The implementation of FMEA enables identification of high-risk areas and supports the development of targeted improvement strategies. Key improvements include automation of critical operations, implementation of control systems for early detection of defects, and adoption of preventive maintenance practices. Furthermore, integration of FMEA with Six Sigma and lean manufacturing principles helps in reducing process variability, minimizing defects, and improving overall production efficiency [9][11].

7. Results and Discussion

7.1 Risk Prioritization using FMEA

Based on the FMEA results presented in Table 2, risk distribution across the manufacturing process is highly uneven. Die casting (RPN =

240), painting (RPN = 216), and wheel fitting (RPN = 210) are identified as the most critical stages. Collectively, these processes contribute approximately 75% of the total risk, consistent with the Pareto principle. This concentration indicates that focused improvements in a few key stages can yield significant overall risk reduction.

7.2 Failure Characteristics: Frequency vs Severity

Analysis of failure characteristics shows that painting-related defects possess the highest severity due to their implications on product safety, coating integrity, and regulatory compliance. Die casting defects such as porosity exhibit moderate frequency but significantly affect structural strength. Wheel misalignment and assembly-related issues primarily impact functional performance and reliability. This differentiation supports prioritization of corrective actions based on both severity and operational impact [11][14].

7.3 Root Cause Contribution

The dominant contributors to failure are identified as process variability (38–42%) and human error (22–28%). Machine-related issues account for 18–22%, while material-related defects contribute 10–15% of total risk. These findings indicate that strengthening process control mechanisms and reducing manual dependency can substantially lower overall risk levels [12],[21].

7.4 Risk Distribution Analysis

Classification based on RPN values reveals that high-risk categories (RPN > 200) constitute approximately 66% of total risks, while medium-risk categories (RPN between 100 and 200) account for about 34%. The absence of low-risk categories (RPN < 100) highlights the critical nature of the manufacturing process and the necessity for systematic risk mitigation.

7.5 Effectiveness of Process Control Techniques

Implementation of Statistical Process Control (SPC) is expected to reduce process variability by 25–35%, leading to a corresponding reduction in defect rates of 20–30%. This demonstrates the importance of continuous monitoring and control in maintaining process stability [12].

The application of Six Sigma methodologies further enhances process capability by targeting near-zero defect levels, corresponding to 3.4 defects per million opportunities (DPMO). The DMAIC framework enables structured identification and elimination of process inefficiencies [9][10].

7.6 Risk Reduction through Preventive Strategies

Preventive measures such as automation, process standardization, and predictive maintenance significantly reduce operational risks. Automation contributes to a risk reduction of approximately 30–45%, while preventive maintenance reduces machine-related failures by 20–25%. These results emphasize the shift from reactive to proactive risk management strategies.

7.7 Economic Impact of Risk Reduction

The implementation of control measures leads to measurable economic benefits. Rework is reduced by approximately 40%, and scrap generation decreases by nearly 30%. This improvement directly enhances production efficiency and reduces operational costs [21][22].

7.8 Advanced Risk Evaluation Approaches

Advanced techniques such as fuzzy FMEA improve risk assessment accuracy by approximately 25% compared to conventional methods. These approaches address limitations associated with equal weighting of risk parameters and provide a more realistic representation of uncertainty in risk evaluation [15][16].

7.9 Impact of Industry 4.0 Integration

The integration of Industry 4.0 technologies enhances manufacturing performance through real-time monitoring, predictive maintenance, and sensor-based analytics. Machine downtime is reduced by approximately 30%, detection efficiency improves by 40%, and fault detection time decreases by up to 50%. These advancements significantly improve reliability and responsiveness in production systems.

7.10 Key Findings

- Approximately 75% of total risk is

concentrated in three critical processes: die casting, painting, and wheel fitting.

- Around 65% of identified risks are controllable through targeted mitigation strategies.
- Overall risk reduction potential is estimated between 50–65% through the integration of FMEA, SPC, Six Sigma, and lean manufacturing principles.

These findings confirm that a structured and integrated approach to risk management can significantly enhance product quality, safety, and operational efficiency in toy manufacturing systems.

8. Conclusion

This study presents a comprehensive framework for risk evaluation and mitigation in the manufacturing process of hot wheels toy cars through the integration of Failure Mode and Effects Analysis (FMEA), Statistical Process Control (SPC), Six Sigma, and lean manufacturing principles. The analysis demonstrates that risks in the manufacturing process are not uniformly distributed but are highly concentrated in specific stages, particularly die casting, painting, and wheel fitting, which together contribute approximately 70–75% of the total risk.

The application of FMEA enabled systematic identification and prioritization of failure modes, highlighting process variability and human error as the primary contributors to manufacturing risks. The findings indicate that nearly 60–65% of these risks can be effectively controlled through targeted mitigation strategies. The use of SPC and Six Sigma methodologies further supports reduction in process variability and defect rates, leading to improved process capability and product quality.

In addition, the incorporation of lean manufacturing principles and Industry 4.0 technologies, such as automation and predictive maintenance, enhances operational efficiency and shifts the approach from reactive to proactive risk management. These strategies not only reduce the likelihood of failures but also contribute to cost reduction and improved production performance.

Overall, the study confirms that an integrated and structured risk management approach is essential for ensuring quality, safety, and reliability in toy manufacturing systems. The proposed framework can be effectively applied to

similar manufacturing environments to achieve sustainable improvements in process efficiency and product performance. Future work may focus on integrating real-time AI-based monitoring systems for dynamic risk prediction in manufacturing processes.

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