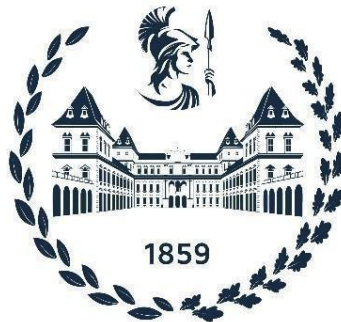


POLITECNICO DI TORINO

Master's Degree in Engineering and Management



Master's Degree Thesis

Linking Quality 4.0 Technologies to Cost of Poor Quality Reduction: A Mechanistic Framework Based on Operational Capabilities

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Summary

The growing diffusion of Industry 4.0 technologies is profoundly transforming quality management into manufacturing systems, introducing new capabilities for monitoring, analysis, and control of production processes. In this context, the Cost of Poor Quality (CoPQ) continues to represent one of the main sources of economic inefficiency for manufacturing organizations, including costs associated with defects, rework, scrap, internal and external failures, and other forms of nonconformity. Although the literature has extensively documented both the benefits of digital technologies and the importance of economic management of quality, a significant fragmentation remains between these two areas of research. Explanations concerning the causal mechanisms through which Quality 4.0 technologies generate measurable economic benefits in terms of CoPQ reduction are still limited.

Against this theoretical background, this thesis develops a mechanistic framework intended to explain how specific Quality 4.0 technologies contribute to the reduction of different categories of CoPQ in manufacturing contexts. The focus is on five key technologies in the digitalization of quality: Internet of Things (IoT), Machine Learning (ML), Manufacturing Execution Systems (MES), Digital Twin, and industrial automation. These five technologies were selected because they represent the most frequently discussed enabling technologies in the Quality 4.0 literature and because, together, they cover the main functional layers of a digitalized quality system: data sensing (IoT), predictive analysis (Machine Learning), production execution and coordination (MES), virtual simulation (Digital Twin), and adaptive process control (automation).

The research adopts a theoretical-conceptual approach based on a systematic literature review conducted according to the PRISMA 2020 protocol (Page et al., 2021), with the inclusion of 84 studies selected from more than 520 records identified in the Scopus, Web of Science, and Google Scholar databases. Through the synthesis of existing knowledge, a framework is developed that organizes the relationships among digital technologies, enabled operational capabilities, transformed quality processes, and affected CoPQ categories.

The proposed framework articulates four causal levels: Quality 4.0 technologies → operational capabilities → transformation of quality processes → CoPQ reduction. The literature review suggests that each technology can enable a specific operational capability: observability (IoT), predictability (Machine Learning), rapid response (automation), operational-design integration (Digital Twin), and coordination (MES), and that these capabilities distinctly influence the

categories of internal, external, prevention, and hidden costs. The main contribution lies in introducing operational capabilities as an intermediate level of analysis, still underdeveloped in previous literature, which explains why the economic value of quality digitalization depends not on the availability of technologies, but on the organizational ability to mobilize the capabilities they make possible.

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Introduction

In the current industrial context, quality represents a key factor in the competitiveness of manufacturing firms, not only from a technical perspective but also from an economic one. In this scenario, the costs associated with poor quality, commonly referred to as the Cost of Poor Quality (CoPQ), constitute one of the main sources of organizational inefficiency. These costs include defects, rework, scrap, internal and external failures, and other forms of nonconformity that compromise the operational and financial performance of organizations (Feigenbaum, 1956; Campanella, 1999).

In the field of quality management, the Prevention–Appraisal–Failure (PAF) model constitutes one of the principal theoretical references for understanding the relationship between investments in quality and the costs arising from nonconformities (Feigenbaum, 1956; Schiffauerova & Thomson, 2006). In particular, the literature shows that an increase in prevention activities is associated with a reduction in internal and external failure costs. Recent empirical evidence supports this relationship: for example, a study conducted in a manufacturing context found that a strongly prevention-oriented strategy enabled an 84.1% reduction in total quality costs, achieving better results than approaches focused mainly on inspection or on mixed strategies (Indra et al., 2025).

At the same time, the emergence of Industry 4.0 technologies has triggered a profound transformation in the ways quality is managed within production systems. Technologies such as the Internet of Things (IoT), Machine Learning, advanced automation, Digital Twin, and Manufacturing Execution Systems (MES) have introduced new possibilities for collecting, processing, and using information across the entire production process. These technologies enable continuous process monitoring, early identification of anomalies, improved traceability, and greater integration among different organizational functions (Baran & Korkusuz Polat, 2022).

This emerging paradigm, commonly referred to as Quality 4.0, transforms quality management from a predominantly reactive approach into an increasingly data-driven system, characterized by the systematic use of data to support monitoring, control, and continuous improvement of quality performance (Salimbeni et al., 2023). In this context, quality is no longer managed exclusively through ex post inspection activities, but through capabilities of observation, prediction, and intervention made possible by digital technologies.

Emerging approaches such as Zero-Defect Manufacturing (ZDM) propose a shift from reactive models to fully predictive and preventive ones, leveraging the potential of digital technologies to minimize defects and waste (Psarommatis et al., 2022). At the same time, advanced tools such as Digital Twins make it possible to simulate and virtually validate products and processes before

physical production, thereby reducing operational risk and improving quality-related decisions (Grieves, 2017).

Despite the growing attention devoted both to the CoPQ and to the digital transformation of quality, literature continues to exhibit significant fragmentation. On the one hand, numerous studies analyze the cost categories associated with poor quality and the strategies for their reduction. On the other hand, a large body of research examines the impact of digital technologies on operational performance and production processes. However, studies that systematically integrate these two perspectives and explicitly explain how Quality 4.0 technologies contribute to the reduction of specific categories of CoPQ remain limited. Existing frameworks tend to treat technology adoption, quality performance, and economic impact as separate domains of analysis, rather than as interconnected elements of a single causal chain. As a result, the intermediate mechanisms that connect the adoption of Quality 4.0 technologies to the reduction of CoPQ remain largely unexplained, with most studies documenting the existence of a relationship without clarifying how it operates. There is a lack of a framework capable of explaining the specific causal mechanism, the 'how' and the 'why,' through which digital technologies reduce CoPQ, rather than merely documenting generic correlations.

In this context, a mechanistic framework is understood as a conceptual model aimed at explaining the causal mechanisms that connect a cause to its effects by identifying the intermediate relationships through which a given outcome is generated. Unlike descriptive frameworks, which merely highlight associations or correlations among variables, a mechanistic framework seeks to clarify how and why such relationships occur. In the context of this research, the objective is not simply to associate Quality 4.0 technologies with the reduction of the CoPQ, but to identify the operational capabilities and transformations of quality processes that mediate this relationship.

In other words: which operational capability does each technology activate? Which quality process does it transform? Which specific categories of CoPQ affect? This gap illustrates an important shortcoming in literature, since investment decisions in Quality 4.0 technologies require an explicit understanding of the causal mechanisms underlying the economic value of digitalization.

In addition, it is necessary to understand how these operational capabilities translate into concrete transformations of quality processes. In the context of this research, quality processes include activities such as process monitoring, inspection and quality control, anomaly detection, information traceability, root cause analysis, and the implementation of corrective and preventive actions. Understanding how these processes are modified by digitalization is a fundamental step toward explaining the link between Quality 4.0 technologies and the reduction of CoPQ.

To help fill this gap, this thesis proposes a mechanistic framework intended to connect digital technologies, operational capabilities, the transformation of quality processes, and categories of CoPQ in manufacturing contexts. Through the systematic integration of the available evidence in the literature, the research develops an interpretive perspective that clarifies how different Quality 4.0 technologies may influence different categories of CoPQ through specific operational mechanisms. The main contribution of the research lies in the development of an integrated conceptual framework that links Cost of Quality theory, the Quality 4.0 paradigm, and the economic impact of quality digitalization, thereby providing a theoretical basis for future empirical validation.

Research Questions

To achieve this objective, the thesis addresses the following research questions:

RQ1: How does quality digitalization transform quality management processes in manufacturing systems?

RQ2: Which operational capabilities are enabled by Quality 4.0 technologies, and what role do they play in the transformation of quality processes?

RQ3: How can Quality 4.0 technologies, through specific operational capabilities, contribute to the reduction of different categories of Cost of Poor Quality in manufacturing contexts?

Structure of the Thesis

The remainder of the thesis is structured as follows. Chapter 1 analyzes the evolution of quality management models, the Prevention–Appraisal–Failure (PAF) framework, the main sources of variability in manufacturing systems, and the implications for the adoption of the Quality 4.0 paradigm. Chapter 2 develops the theoretical background related to Industry 4.0 technologies and the Quality 4.0 paradigm, analyzing the operational capabilities enabled by digitalization and the main quality management models adapted to digital contexts. Chapter 3 describes the methodological approach adopted, including the literature review process, the source selection criteria, and the framework development procedure. Chapter 4 presents the mechanistic framework proposed by the research, defining the causal relationships among Quality 4.0 technologies, operational capabilities, the transformation of quality processes, and specific categories of CoPQ. Chapter 5 critically analyzes the empirical evidence in the literature regarding the impact of Quality 4.0 technologies on the different categories of CoPQ in manufacturing contexts. Chapter

6 presents the conclusions of the research, summarizing its main theoretical and managerial contributions and proposing directions for future studies in the field of Quality 4.0 and the economic management of quality.

1. Understanding Quality Management in Manufacturing

1.1. Evolution of quality management models

Quality management represents one of the most established topics in managerial and manufacturing literature. Over time, the concept of quality and the ways in which it is managed have undergone significant evolution, reflecting the technological, organizational, and economic changes that have characterized production systems. What is now defined as Quality Management is the result of an evolutionary path that has progressively expanded the role of quality from a simple product control activity to a strategic capability integrated into business processes.

In the early stages of industrial development, quality was primarily ensured through inspection activities aimed at identifying defective products. With the increase in production complexity and international competition, this approach gradually evolved toward models oriented towards prevention, statistical process control, and continuous improvement. At the same time, growing attention to the economic impacts of poor quality fostered the development of specific frameworks for measuring quality-related costs, culminating in the modern models of Cost of Quality (CoQ) and Cost of Poor Quality (CoPQ) (Campanella, 1999; Farooq, 2017).

The evolution of quality has concerned not only tools and methodologies, but also the way organizations interpret their role in managing quality performance. Approaches such as Total Quality Management (TQM), ISO 9000, Lean Manufacturing, and Six Sigma have progressively shifted attention from the simple identification of defects toward the systemic management of processes, the reduction of variability, and the continuous improvement of operational performance (Baran & Korkusuz Polat, 2022).

In recent years, the diffusion of technologies associated with Industry 4.0 has introduced new opportunities and new challenges for Quality Management. The availability of real-time data, the interconnection of production systems, and advanced analytical capabilities have fostered the emergence of the Quality 4.0 paradigm, which seeks to integrate traditional quality principles with the potential offered by digital transformation (Salimbeni et al., 2023). In this context, quality is increasingly managed through data-supported capabilities for monitoring, prediction, and intervention, moving beyond approaches based exclusively on final inspection.

Understanding the evolution of quality management models therefore represents a fundamental step in interpreting how digital technologies can contribute to improving quality performance and reducing

CoPQ in contemporary manufacturing contexts.

The following sections analyze the evolution of the main quality models, from traditional approaches based on inspection and prevention to the more recent paradigms linked to digitalization and Quality 4.0.

1.1.1. From Inspection to Prevention-Based Quality Management

Throughout the evolution of Manufacturing Quality, Quality Control has been interpreted through different theoretical and operational perspectives, developed in response to changes in production systems and to the growing need to ensure conformity, reliability, and efficiency. Among these, Inspection-Based Quality Control and Prevention-Based Quality Control represent two fundamental approaches that have profoundly influenced the development of modern Quality Management. Although both pursue the objective of reducing nonconformities and improving product quality, they differ substantially in the timing and way they address the problem of quality (International Organization for Standardization [ISO] 9000, 2015; Baran & Korkusuz Polat, 2022).

Inspection-Based Quality Control is based on verifying product conformity against predefined requirements and specifications through measurement, testing, sampling, and inspection activities. Historically, this approach represented the main tool used by manufacturing organizations to ensure quality, especially in contexts characterized by high production volumes and limited process monitoring capabilities (Farooq et al., 2017). Its main advantage lies in the ability to identify defective products before delivery to the customer, thereby reducing risks associated with nonconformity and ensuring compliance with regulatory, safety, and traceability requirements (ISO 9000, 2015).

More recent contributions have sought to make inspection-based approaches more targeted and cost-effective: Verna et al. (2021), for instance, propose inspection strategy maps that combine defect probabilities obtained from prediction models with inspection variables, providing both an analysis tool for benchmarking existing inspection strategies and a design tool for achieving desired cost and effectiveness targets.

However, the literature highlights that this approach presents important structural limitations. Because inspection generally takes place after the defect has appeared, it makes it possible to identify nonconformities but not necessarily to eliminate their causes. As a result, rework, scrap, operational downtime, and other forms of inefficiency may continue to occur even in the presence of effective inspection procedures (Farooq et al., 2017; Bris et al., 2022). In addition, an increase in control activities may raise appraisal costs without guaranteeing a proportional reduction in total quality costs (Farooq, 2017). These limitations progressively encouraged the emergence of prevention-oriented approaches.

Prevention-Based Quality Control is founded on the principle that quality should be built into processes rather than verified exclusively on the final product. From this perspective, the objective is not to identify the defect once it has been generated, but to reduce its probability through control of the conditions that produce it (Campanella, 1999). The preventive approach places particular importance on process standardization, staff training, root cause analysis (Root Cause Analysis – RCA), variability reduction, and Continuous Improvement practices, with the aim of acting on the sources of poor quality and achieving a stable improvement in production system performance (Baran & Korkusuz Polat, 2022).

The economic relevance of prevention is grounded in the Prevention–Appraisal–Failure (PAF) model, according to which investments in preventive activities can help reduce, over the long term, the costs associated with internal and external failures, thereby improving the overall efficiency of the organization (Campanella, 1999). Although developed in a context preceding industrial digitalization, the model continues to represent one of the main theoretical references for interpreting the relationship between investments in quality and economic outcomes (Schiffauerova & Thomson, 2006).

Recent empirical evidence supports this perspective. Studies conducted in manufacturing contexts show that greater attention to preventive activities is associated with a significant reduction in failure costs and an improvement in overall economic performance, suggesting that prevention should be considered a strategic investment rather than a simple operating cost (Indra et al., 2025).

Overall, the transition from Inspection-Based Quality Control to Prevention-Based Quality Control represents one of the main conceptual evolutions in the history of Quality Management. Although the two approaches perform complementary functions within quality management systems, the evolution of literature highlights a growing emphasis on prevention as a tool to reduce the causes of poor quality and improve organizational performance over the long term. This evolution progressively paved the way for more integrated and systemic models of quality, which are analyzed in the following section.

1.1.2. The Evolution Toward Integrated Quality Management

The evolution from inspection-based Quality Control toward prevention-oriented approaches progressively led to the development of a systemic perspective on quality. In this view, Manufacturing Quality does not depend exclusively on verification of the final product or on individual control activities, but on the coordinated interaction among processes, people, methodologies, information systems, and managerial practices. Quality therefore becomes a distributed organizational capability, supported by formalized procedures, performance measurement, continuous improvement, and the involvement of different business functions.

One of the main references for this perspective is the ISO 9000 series, developed to provide principles,

guidelines, and requirements for building quality management systems. In the industrial context, ISO 9000 should not be interpreted merely as a certification standard, but as an organizational model oriented toward process standardization, procedure documentation, definition of responsibilities, and the systematic management of nonconformities. The literature shows that ISO 9000 certification became established after the diffusion of Total Quality Management (TQM), responding to the need for an international quality standard in global markets (Faciane, 2018).

A second central approach is represented by Six Sigma, a methodology aimed at reducing process variability and defects using statistical and analytical tools. Through the DMAIC cycle (Define, Measure, Analyze, Improve, Control), Six Sigma provides a methodological structure for identifying the root causes of nonconformities, implementing corrective actions, and monitoring their results over time. The distinctive feature of this approach lies in its ability to link quality improvement to quantitative measurements of process performance, thereby supporting data-based decisions and the systematic control of variability (Farooq et al., 2017).

Alongside Six Sigma, Lean Manufacturing focuses on the elimination of waste, the simplification of operational flows, and the continuous improvement of value-added activities. While Six Sigma primarily aims to reduce variability and defects, Lean is oriented toward increasing the overall efficiency of the production system through the reduction of unnecessary activities, lead times, and operational inefficiencies. The literature shows that this approach contributes not only to improving operational performance, but also to the diffusion of an organizational culture oriented toward continuous improvement (Abualsauod, 2026).

The integration of Six Sigma and Lean Manufacturing, commonly defined as Lean Six Sigma (LSS), combines variability reduction with waste elimination, making it possible to address quality and efficiency problems simultaneously. This complementarity enables organizations to improve process performance through an integrated approach that combines quantitative analysis, statistical control, and the optimization of operational flows (Abualsauod, 2026).

An even broader perspective is offered by TQM, which interprets quality as a responsibility distributed throughout the entire organization. TQM integrates customer orientation, leadership, employee involvement, process management, continuous improvement, and organizational learning within a single conceptual framework. More than a set of specific tools, it represents a managerial philosophy aimed at building a quality culture capable of permeating all business activities (Faciane, 2018).

The literature analysis shows that ISO 9000, Six Sigma, Lean Manufacturing, and TQM should not be interpreted as alternative approaches, but rather as complementary elements of an integrated quality management system. ISO 9000 provides the organizational and documentary structure; Six Sigma offers

tools for variability control; Lean improves flow and reduces waste; and TQM integrates these elements within an organizational culture oriented towards quality. The contemporary approach to quality is therefore based on the combination of standardization, continuous improvement, quantitative analysis, and organizational involvement.

The relevance of this integration becomes particularly evident in the context of Quality 4.0. The growing availability of real-time data, digital traceability, and advanced analytical capabilities makes it possible to strengthen traditional Quality Management approaches by increasing visibility, predictive capability, and process control. From this perspective, digitalization does not replace established quality models but extends their potential through tools that support timelier and data-based decisions (Salimbeni et al., 2023).

Table 1. Evolution of Quality Management Approaches from Standardization to Quality 4.0

Approach	Focus	Main tools / methods	Typical metrics	Strength	Main limitations
<i>ISO 9000</i>	Standardization of the quality system	Procedures, audits, documentation, management of nonconformities	Nonconformities, audit findings, complaints, process indicators	Creates a formalized management structure.	Risk of a bureaucratic approach if applied solely for certification purposes.
<i>Six Sigma</i>	Reduction of variability and defects	DMAIC, SPC, FMEA, Root Cause Analysis	Defect rate, DPMO, process capability indicators	Strong analytical and quantitative capability.	Requires statistical expertise and the availability of reliable data.
<i>Lean Manufacturing</i>	Elimination of waste and improvement of flow	Value Stream Mapping, JIT, Kanban, Kaizen	Lead time, throughput, waste indicators	Improves process efficiency and speed.	May reduce waste without fully addressing variability.
<i>Total Quality Management (TQM)</i>	Organizational culture of quality	Leadership, customer focus, employee involvement, continuous improvement	Customer satisfaction, quality performance, process improvement	Integrates quality throughout the organization.	Results are often difficult to measure quantitatively.

Lean Six Sigma (LSS)	Integration of waste reduction and variability reduction	DMAIC integrated with Lean tools	Defect rate, DPMO, throughput, cost reduction	Combines operational efficiency and statistical control.	Requires cultural alignment, training, and leadership.
Quality 4.0	Digitalization of quality management	IoT, MES, Machine Learning, Digital Twin, automation	Real-time monitoring, predictive indicators, defect detection, process visibility	Improves observability, predictive capability, and decision support.	Requires technological integration and digital skills.

Note: Compiled by the author based on the literature review.

In summary, the systemic perspective on quality overcomes the dichotomy between inspection and prevention by interpreting quality as the outcome of an integrated organizational system involving interdependent processes, people, and managerial practices (Baran & Korkusuz Polat, 2022). The evolution toward increasingly integrated and data-driven approaches constitutes theoretical foundation on which both the analysis of the CoPQ and the subsequent examination of the role of digital technologies in reducing the costs of poor quality are developed.

1.1.3. Understanding the Cost of Poor Quality (CoPQ): Framework and Economic Implications

The Cost of Poor Quality represents one of the most relevant concepts for understanding the relationship between quality and economic performance in manufacturing systems. While inspection-based, prevention-based, and integrated-system perspectives describe how quality can be managed, CoPQ makes it possible to understand the extent to which poor quality affects the economic results of the organization. In this sense, defects, rework, scrap, complaints, delays, and operational inefficiencies can all be translated into monetary terms, making visible the financial impact of nonconformities on production processes.

The literature on quality-related costs highlights that the cost of quality does not derive primarily from the investments needed to ensure conformity, but rather from the losses generated by poor quality. In this sense, CoPQ can be defined as the set of costs that would be eliminated if products and processes were free of defects or inefficiencies (Thomasson & Wallin, 2013). This perspective is particularly relevant from a managerial standpoint because it makes it possible to identify the most critical areas of the production process, set priorities for intervention, and support decisions related to prevention,

control, and quality improvement. Monitoring quality costs can also contribute to reducing complaints, improving operational performance, and strengthening overall financial performance (Bris et al., 2022).

One of the most widely used classifications of quality costs is the Prevention–Appraisal–Failure (PAF) model, which distinguishes four main categories:

- **Prevention Costs:** costs incurred to avoid the generation of nonconformities, such as training, preventive maintenance, quality planning, and process improvement activities.
- **Appraisal Costs:** costs associated with verification and control activities aimed at identifying nonconformities, such as inspections, audits, and tests.
- **Internal Failure Costs:** costs arising from defects detected before delivery to the customer, such as scrap, rework, and production stoppages.
- **External Failure Costs:** costs associated with defects detected after delivery, including complaints, warranties, returns, loss of reputation, and reduced sales (Farooq et al., 2017).

Table 2. Main CoPQ Categories According to the PAF Model.

Category	Definition	Examples in the manufacturing context	Managerial implication
<i>Prevention Costs</i>	Costs incurred to prevent the generation of nonconformities.	Training, preventive maintenance, quality planning, process improvement.	Reduce the likelihood that defects will be generated.
<i>Appraisal Costs</i>	Costs incurred to detect nonconforming units.	Inspections, tests, audits, dimensional checks, acceptance testing.	Identify defects before delivery.
<i>Internal Failure Costs</i>	Costs caused by defects detected before delivery to the customer.	Scrap, rework, line stoppages, production relaunched.	Reduce internal inefficiencies and production waste.
<i>External Failure Costs</i>	Costs caused by defects detected after delivery to the customer.	Warranties, complaints, returns, loss of reputation, loss of sales	Reduce economic and reputational impacts on the market.

Note: Compiled by the author based on Porter and Rayner (1992); Farooq et al. (2017); Mufato Reis et al. (2024).

The relationship among these categories is represented in Figure 1. As shown by the model, as the level of quality increases, failure costs tend to decrease, while investments in prevention and appraisal increase. The total cost of quality therefore takes on a convex shape, highlighting the existence of an economic equilibrium point (“optimum quality”) at which the overall cost of the system is minimized. From this perspective, quality management can be interpreted as an optimization problem between preventive investments and the costs arising from poor quality.

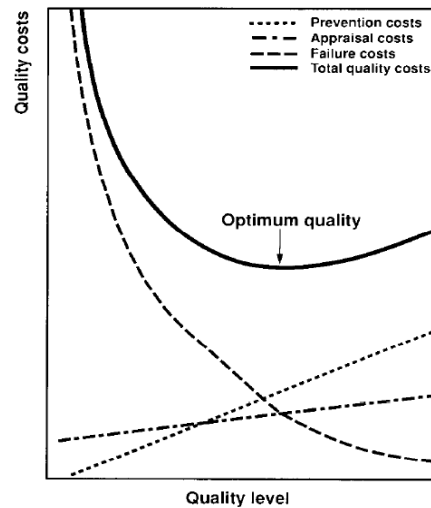


Figure 1. Relationship among prevention, appraisal, and failure costs in the PAF model.

Note: Adapted from Porter and Rayner (1992).

1.1.3.1 Operational manifestations and economic impact

In manufacturing systems, internal failure costs are concretely manifested in scrap, rework, reinspection, production stoppages, and productivity losses. These events lead to inefficient use of materials, human resources, and production capacity, propagating inefficiencies throughout the entire production system without generating added value (Bris et al., 2022; Farooq et al., 2017). External failure costs -complaints, returns, warranty interventions, and product recalls- produce effects that extend beyond the economic structure of the firm, compromising corporate reputation, customer trust, and long-term competitiveness. In markets characterized by intense competition and growing attention to quality, such reputational consequences can be particularly significant (Campanella, 1999).

Alongside directly observable costs, the literature highlights a significant component of hidden quality costs, frequently associated with production delays, operational inefficiencies, lost business opportunities, and reduced customer satisfaction. Although more difficult to identify and quantify, these costs may represent a substantial share of the overall economic impact of poor quality (Campanella, 1999). Empirical evidence indicates that CoPQ may reach values between 10% and 30% of company turnover, depending on the industrial sector, the maturity level of the quality system, and the

organization's ability to measure and control such costs (Sower et al., 2007; Bris et al., 2022). In many organizations, a significant portion of these losses remain hidden or is not adequately monitored, leading to an underestimation of the actual economic impact of poor quality.

Table 3. Operational and Economic Impact of CoPQ in Manufacturing Systems

CoPQ Category	Typical Manifestations	Operational Impact	Economic Impact
<i>Internal Failure Costs</i>	Scrap, rework, reinspection, downtime	Reduced productivity and resource utilization	<i>Increased production costs</i>
<i>External Failure Costs</i>	Returns, warranty claims, recalls, complaints	Customer dissatisfaction and reputation damage	<i>Revenue loss and additional service costs</i>
<i>Hidden Quality Costs</i>	Delays, inefficiencies, lost opportunities	Reduced organizational effectiveness	<i>Underestimated financial losses</i>

Note: Compiled by the author based on Campanella (1999), Farooq et al. (2017), Sower et al. (2007), and Bris et al. (2022).

From an operational perspective, CoPQ can be interpreted as a synthetic indicator of the organization's ability to control process variability and prevent the generation of defects. High levels of CoPQ are frequently associated with unstable processes, limited capability to detect anomalies, ineffective information management, and reduced integration among different business functions. Conversely, its reduction generally signals improved operational performance and the organization's ability to transform quality into a sustainable competitive advantage (Farooq et al., 2017).

1.1.3.2 Measurement challenges and process-based nature

The distinction between visible costs and hidden costs highlights that the CoPQ problem concerns not only the classification of costs, but also the organization's ability to collect reliable data and correctly attribute losses to the processes that generated them. The quantification of quality costs is often hindered by the lack of standardization, the use of non-comparable internal methodologies, and the difficulty of integrating data from different business functions. Despite the benefits associated with its monitoring, this practice continues to receive limited attention in many organizations (Bris et al., 2022; Thomasson & Wallin, 2013).

For this reason, the measurement of CoPQ assumes a strongly process-based nature. It is not sufficient to record the final cost of scrap or rework; it is necessary to understand where the defect was generated, at which stage it was detected, which resources were used to correct it, and what consequences it produced along the production process. This approach makes it possible to link operational causes, nonconformity events, and economic impacts, transforming CoPQ from a simple accounting tool into a decision-support tool.

The quantification of CoPQ can also be used to compare different quality management strategies: Farooq et al. (2017) show how the framework makes it possible to evaluate simultaneously the appraisal costs and failure costs associated with different inspection strategies, identifying the most economically sustainable solutions. Recent empirical evidence supports this usefulness: in a study conducted in an Indonesian manufacturing context, a prevention-focused strategy reduced total quality costs by 84.1%, from USD 0.0751 to USD 0.0119 per product, and improved conformity from 96.11% to 99.75% (Indra et al., 2025), suggesting that targeted investments in preventive activities can significantly reduce failure costs.

In the context of Industry 4.0, the growing availability of sensors, traceability systems, and digital platforms creates new opportunities to collect more accurate information on quality costs. However, the availability of data does not automatically eliminate the measurement problem: it requires models capable of transforming operational information into economic knowledge useful for Quality Management (Mufato Reis et al., 2024). For this reason, CoPQ constitutes an essential theoretical basis for analyzing the contribution of digital technologies to reducing the different categories of CoPQ.

In summary, CoPQ makes it possible to transform poor quality from a technical-operational problem into an economic and managerial problem. Through the classification of costs, the distinction between visible and hidden components, and the quantification of the financial impacts of nonconformities, the framework provides the essential basis for evaluating the effectiveness of quality strategies and the potential contribution of emerging technologies, a topic that will be explored further in the course of the analysis.

Table 4. Evolution of Quality Management Paradigms and Their Main Characteristics

Period	Focus	Main objective	Main limitations
<i>Inspection-Based</i>	Product control	Identify defects	Reactive approach
<i>Prevention-Based</i>	Process control	Prevent defects	Limited visibility
<i>Integrated Quality Management</i>	Organizational system	Continuous improvement	Dependence on periodic data

<i>CoPQ Perspective</i>	Economic impact	Quantify quality	poor	Measurement difficulty
<i>Quality 4.0</i>	Data and digital technologies	Proactive predictive quality	and	Technological complexity

Note: Compiled by the author based on the synthesis of the literature on the evolution of Quality Management models.

The evolution of quality paradigms does not represent a simple linear succession of approaches, but rather a progressive broadening of the perspective through which organizations interpret the role of quality. From final-product control to prevention, from integrated quality management to economic evaluation through the CoPQ, and up to the contemporary models of Quality 4.0, each stage has expanded the understanding of the relationship between quality, processes, and organizational performance. In this perspective, digitalization does not constitute a break with previous paradigms, but an evolutionary development that enables organizations to manage quality with greater timeliness, visibility, and predictive capability.

1.2. Manufacturing quality in contemporary systems

1.2.1. Sources of quality variability in manufacturing systems

The ability to ensure high and consistent levels of quality represents one of the main challenges of contemporary manufacturing systems. Despite the adoption of standardized procedures, advanced control systems, and established quality management practices, production processes remain inevitably subject to different forms of quality variability that affect final product conformity and operational stability. Quality can therefore be interpreted as the result of the organization's ability to control and reduce the sources of variation that arise throughout the entire production system (Montgomery, 2019).

Variability is an intrinsic characteristic of any manufacturing process. No production system can generate perfectly identical results over time, since every operational activity is influenced by multiple technical, human, and organizational factors that determine significant deviations from nominal operating conditions (Shewhart, 1931). Although part of these variations may be considered physiological, excessive levels of variability increase the probability of generating defects, nonconformities, and operational inefficiencies.

One of the main sources of variability is process variability, that is, fluctuations associated with the operating conditions of the production process. Parameters such as temperature, pressure, processing speed, cycle times, and setup conditions can significantly influence the qualitative characteristics of the

final product. In manufacturing contexts characterized by tight tolerances, even limited deviations from optimal values can compromise the process's ability to maintain conforming and repeatable results over time (Montgomery, 2019).

Supplier variability constitutes another source of instability. Differences in the physical, chemical, or dimensional properties of raw materials and components can affect process stability and final product quality, generating different outcomes even under the same operating conditions. Supply consistency therefore constitutes an essential element for maintaining conformity with the required specifications (Juran & Godfrey, 1999).

Human variability is associated with differences in skills, experience, interpretation of operating procedures, and the ability to perform standardized tasks. Although automation has progressively reduced the incidence of some forms of human error, the contribution of operators remains decisive in supervision, maintenance, inspection, and the management of operational exceptions (Evans & Lindsay, 2020).

Equipment variability also represents a relevant source of instability. Phenomena such as tool wear, loss of precision in measuring instruments, calibration issues, and degradation in machine performance can compromise process stability and directly influence the quality of production outcomes. A significant share of the nonconformities observed in manufacturing systems is associated with the difficulty of maintaining stable operating conditions and consistent equipment performance over time (Farooq et al., 2017).

Beyond the sources traditionally associated with production processes, the growing complexity of modern supply chains has introduced forms of organizational variability. The presence of multiple suppliers, the geographical distribution of production activities, the fragmentation of information flows, and the need to coordinate different actors along the value chain increase the risk of operational inconsistencies, delays, and deviations from planned conditions.

From an economic perspective, variability assumes strategic importance because it denotes one of the main origins of the costs associated with poor quality. Processes characterized by high instability tend to generate higher levels of scrap, rework, production stoppages, operational inefficiencies, and customer complaints, thereby contributing directly to the increase in CoPQ (Bris et al., 2022). Reducing variability therefore constitutes a fundamental objective both for improving quality performance and for enhancing the organization's economic performance.

Table 5. Main Sources of Quality Variability in Manufacturing Systems

<i>Source of Variability</i>	<i>Typical Causes</i>	<i>Potential Quality Impact</i>
<i>Process Variability</i>	Temperature, pressure, setup conditions, cycle time	Defects, process instability
<i>Supplier Variability</i>	Material inconsistency, component variation	Non-conformities, reduced product consistency
<i>Human Variability</i>	Skills, experience, procedural interpretation	Execution variability, operational errors
<i>Equipment Variability</i>	Wear, calibration issues, performance degradation	Process drift, measurement errors
<i>Organizational Variability</i>	Information fragmentation, coordination issues, supply chain complexity	Delays, inconsistencies, reduced process visibility

Note: Compiled by the author based on Shewhart (1931), Juran and Godfrey (1999), Montgomery (2019), Evans and Lindsay (2020), and Farooq et al. (2017).

In summary, quality in manufacturing systems is influenced by a multiplicity of sources of variability affecting processes, materials, human resources, equipment, and organizational structures. Understanding these factors represents an essential prerequisite for analyzing the challenges associated with quality management in contemporary production contexts and provides the basis for understanding how increasing operational complexity may influence the generation of defects, inefficiencies, and CoPQ.

1.2.2. Quality management as a competitive driver

In the contemporary manufacturing context, quality can no longer be interpreted exclusively as a technical requirement aimed at ensuring product conformity or reducing the number of defects. The intensification of global competition, rising customer expectations, the growing complexity of supply chains, and the shortening of product life cycles have progressively transformed quality into a strategic element capable of directly influencing firms' competitiveness. As a result, Quality Management has evolved from a predominantly operational function into an organizational capability able to generate sustainable competitive advantages and improve the firm's overall performance (Powell, 1995).

The literature highlights that organizations adopting advanced quality management practices tend to achieve superior results compared with competitors in terms of operational efficiency, process

reliability, customer satisfaction, and economic performance. Quality acts as a cross-cutting factor that simultaneously influences multiple dimensions of business performance, contributing to value creation both within the organization and along the entire value chain (Kaynak, 2003).

From an operational standpoint, processes characterized by high levels of quality tend to display lower variability, fewer operational interruptions, and lower scrap levels, thereby fostering a more efficient use of productive resources and higher productivity. At the same time, the ability to deliver products that are reliable and aligned with customer expectations helps strengthen corporate reputation, increase customer satisfaction, and consolidate long-term relationships. These benefits are also reflected in economic performance, as the reduction of inefficiencies and the increase in perceived value support greater profitability and better market outcomes (Evans & Lindsay, 2020).

The growing attention to the strategic role of quality has fostered the integration of Quality Management principles into strategic management theories. In particular, the Resource-Based View (RBV) offers a relevant perspective for understanding how quality can constitute a source of sustainable competitive advantage. According to this approach, competitive advantage derives from the availability of resources and capabilities that are difficult for competitors to imitate. From this perspective, quality is not interpreted as a simple set of tools or procedures, but as a complex organizational capability that emerges from the integration of knowledge, skills, processes, corporate culture, and managerial practices (Powell, 1995).

This interpretation makes it possible to move beyond the traditional view of quality as a specialist function. Quality performance in fact depends on the organization's ability to develop coordinated systems of learning, continuous improvement, and knowledge management. Such capabilities are often difficult for competitors to replicate and can therefore become sources of durable competitive advantage (Powell, 1995).

Within the Resource-Based View, operational capabilities can be defined as the set of competencies, organizational routines, and mechanisms that enable the firm to use its resources effectively to achieve specific operational objectives. Unlike technologies, which represent resources or tools available to the organization, operational capabilities describe what the organization is actually able to do through those resources. In the context of Quality Management, such capabilities may include, for example, real-time process monitoring, timely anomaly identification, the integration of information from different sources, support for data-based decisions, and the effective implementation of corrective and preventive actions.

This distinction assumes particular relevance in the context of digital transformation. Industry 4.0 technologies do not automatically produce improvements in quality; their impact depends on the organization's ability to transform technological functionalities into new operational capabilities. From

this perspective, operational capabilities represent the mechanism through which digital technologies can influence quality processes and contribute to the reduction of different categories of CoPQ. This relationship constitutes one of the central elements of the framework developed in this research.

Further empirical evidence shows that the effects of Quality Management on organizational performance are frequently mediated by factors such as process integration, employee involvement, customer orientation, and the ability to use reliable information in decision-making processes. The benefits of quality therefore do not emerge automatically from the adoption of specific practices, but from their integration into the organizational capabilities that support the continuous improvement of performance (Prajogo & Sohal, 2006).

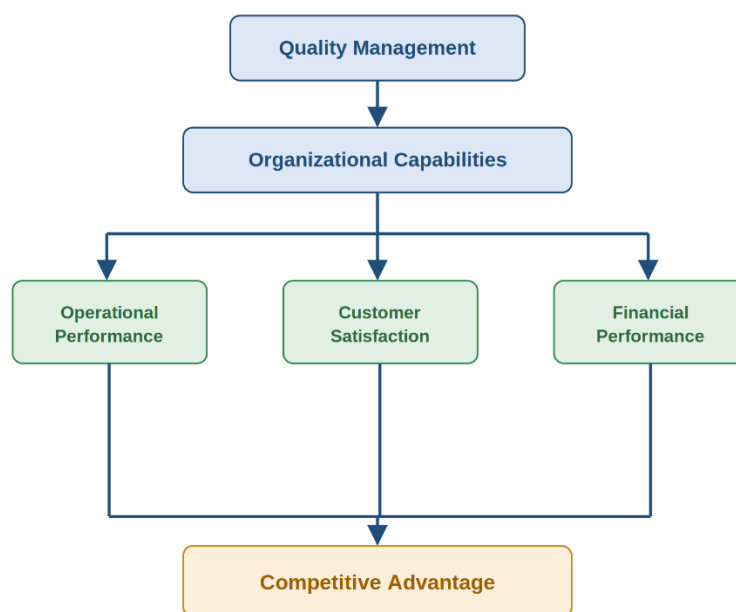


Figure 2. Quality Management as a Source of Competitive Advantage

Note: Compiled by the author based on Powell (1995), Kaynak (2003), and Prajogo and Sohal (2006).

In this scenario, Quality Management assumes a strategic role that goes beyond the reduction of defects or the CoPQ: quality becomes an enabling factor for operational efficiency, customer satisfaction, economic growth, and the construction of sustainable competitive advantages. Understanding quality as an organizational capability therefore represents a fundamental step in analyzing the contribution of digital technologies to the transformation of quality management systems. If quality constitutes a source of competitive advantage, it becomes essential to understand how technologies associated with Industry 4.0 can strengthen the organizational capabilities that drive its improvement. This issue constitutes the starting point for the next chapter, devoted to analyzing the relationship among digital transformation, Quality 4.0, and the improvement of quality performance in manufacturing systems.

This perspective is particularly relevant in the context of the present research. If quality can be interpreted as a strategic organizational capability, it becomes necessary to understand which operational capabilities enable organizations to improve quality performance and reduce the CoPQ. In this context, digital technologies do not generate value exclusively through their technical characteristics, but through the capabilities they make it possible to develop and strengthen within organizational processes. This relationship between technologies, operational capabilities, and quality outcomes constitutes one of the central elements of the framework proposed in this thesis.

1.2.3. Toward Quality 4.0: Challenges and Emerging Opportunities

Despite the significant progress introduced by contemporary models, the growing complexity of manufacturing systems poses challenges that traditional approaches struggle to address fully. The multiplicity of sources of variability analyzed in the previous section, the high level of product variety, the integration of global supply chains, and the availability of large volumes of data make it increasingly difficult to ensure complete visibility of processes through conventional tools. At the same time, the measurement of CoPQ continues to be hindered by the difficulty of collecting complete, reliable, and timely information on the costs associated with defects, rework, and complaints (Thomasson & Wallin, 2013). In many production systems, a relevant share of the losses associated with poor quality therefore remains unidentified or is not correctly attributed to the processes that generated it.

These critical issues have fostered growing interest in the integration of established Quality Management principles with the digital technologies associated with Industry 4.0. The availability of sensors, interconnected systems, real-time data collection platforms, and advanced analytical capabilities offers new opportunities to support continuous process monitoring, improve operational visibility, and identify anomalies in a timely manner (Salimbeni et al., 2023). In this context, the Quality 4.0 paradigm emerges. It does not replace traditional approaches but expands their potential by enabling higher levels of traceability, predictive capability, and data-based decision support.

A significant gap nevertheless emerges in the literature: although the potential of digital technologies to improve quality is widely recognized, the mechanisms through which these technologies contribute to the reduction of different categories of CoPQ remain poorly understood. It is still unclear how Industry 4.0 technologies influence operational capabilities, transform quality processes, and affect the economic impact of poor quality. Digital technologies do not generate automatic improvements; their value depends on the organization's ability to transform them into new operational capabilities that stand between the technological tool and qualitative and economic outcomes.

There is therefore a need to analyze digital technologies not only as tools, but also as enabling factors for new ways of managing quality. This perspective constitutes the starting point of the next chapter,

which is devoted to the analysis of the Quality 4.0 paradigm and of the main Industry 4.0 technologies applied to manufacturing quality management and to the reduction of the CoPQ.

2. Quality 4.0 and Industry 4.0 Technologies

The growing complexity of contemporary manufacturing systems has profoundly transformed the way organizations manage quality. As highlighted in the previous chapter, quality represents a strategic organizational capability that directly influences operational performance, customer satisfaction, business competitiveness, and the reduction of the CoPQ. However, maintaining high levels of quality is becoming increasingly complex in contexts characterized by high product variety, global supply chains, interconnected processes, and the growing availability of operational data.

In response to these challenges, the Industry 4.0 paradigm has emerged, described as the fourth industrial revolution, and characterized by the integration of physical and digital systems, the advanced connectivity of production resources, and the extensive use of data to support decision-making processes. Through technologies such as the Internet of Things (IoT), Artificial Intelligence (AI), Machine Learning (ML), Digital Twin, and Manufacturing Execution Systems (MES), organizations can collect, process, and use information from production processes in real time, overcoming many of the limitations associated with traditional quality control systems (Kagermann et al., 2013; Xu et al., 2018).

The integration of Quality Management principles with digital technologies has fostered the emergence of the Quality 4.0 paradigm, interpreted as the application of Industry 4.0 technologies to quality management processes. The objective is not simply the automation of existing activities, but the strengthening of the monitoring, analysis, prediction, and decision-support capabilities needed to prevent defects, reduce variability, and improve quality performance (Radziwill, 2018; Salimbeni et al., 2023).

However, the literature shows that the benefits associated with Quality 4.0 do not derive automatically from the adoption of technologies, but from their integration with processes, competencies, and managerial practices. Consequently, understanding the mechanisms through which different technologies contribute to quality improvement illustrates a central issue for both research and industrial practice (Sony et al., 2020).

Considering these considerations, this chapter analyzes the Industry 4.0 paradigm, the concept of Quality 4.0, and the main digital technologies relevant to quality management, with the objective of building the theoretical foundation necessary for the development of the conceptual framework proposed by this research.

2.1. Industry 4.0 paradigm and enabling technologies

The Industry 4.0 paradigm represents a profound transformation of manufacturing systems, based on the integration of digital technologies, physical systems, operational data, and advanced analytical capabilities. Unlike previous phases of industrialization, founded primarily on mechanization, electrification, and automation, Industry 4.0 introduces a production logic characterized by interconnection, real-time data exchange, vertical and horizontal systems integration, and increasing decision-making autonomy of production processes (Kagermann et al., 2013; Hermann et al., 2016; Xu et al., 2018).

From a technological standpoint, Industry 4.0 does not coincide with a single technology, but with a set of enabling technologies that, when integrated, make it possible to build intelligent, connected, and data-driven manufacturing systems. The literature frequently identifies among the main enabling technologies the Internet of Things (IoT), Cyber-Physical Systems (CPS), Cloud Computing, Big Data Analytics, Artificial Intelligence (AI), Machine Learning (ML), Digital Twin, Autonomous Robots, Additive Manufacturing, Augmented Reality (AR), Virtual Reality (VR), Blockchain, Cybersecurity, and systems for vertical and horizontal integration of production processes (Rüßmann et al., 2015; Frank et al., 2019; Baran & Korkusuz Polat, 2022).

These technologies perform different functions within production systems. Some act as infrastructures for data collection and integration; others support advanced analytics, simulation, automation, or decision-making processes. For example, IoT enables the continuous collection of data from machines, sensors, and products; Cloud Computing provides storage and scalability; Big Data Analytics, AI, and ML make it possible to extract useful information from large volumes of data; Digital Twin enables the virtual simulation of processes; while MES systems connect the operational level with the managerial level (Frank et al., 2019; Salimbeni et al., 2023).

In the context of Quality Management, the relevance of Industry 4.0 technologies must be assessed not only according to their degree of technological innovation, but above all in terms of their ability to support critical activities such as process monitoring, anomaly detection, traceability, variability control, defect prediction, decision support, and the reduction of the CoPQ. This perspective is consistent with the literature on Quality 4.0, which interprets the digitalization of quality as the transition from predominantly retrospective and document-based systems to systems capable of collecting, analyzing, and using quality data in real time (Radziwill, 2018; Sony et al., 2020; Salimbeni et al., 2023).

The literature also highlights that not all Industry 4.0 technologies contribute to quality management in the same way. Some technologies primarily affect production methods, others communication among systems, and others decision support or information management. Consequently, the relevance of a technology for Quality Management must be evaluated according to its ability to influence quality

monitoring, defect prevention, information traceability, and CoPQ reduction.

Considering the literature reviewed, this research focuses the in-depth analysis on five technologies: Internet of Things (IoT), Machine Learning/Artificial Intelligence (ML/AI), Automation Technologies, Digital Twin, and Manufacturing Execution Systems (MES).

The selection is guided by two main criteria. First, these technologies cover the principal informational functions required for the digitalization of quality, including data acquisition, operational integration, predictive analysis, virtual simulation, and automated response to quality problems. Second, they display a particularly direct relationship with the processes of monitoring, variability control, defect prevention, traceability, and reduction of the CoPQ, which constitute the focus of this research.

Specifically, IoT enables the continuous acquisition of data from production processes; MES systems support operational integration and information traceability; Machine Learning/Artificial Intelligence enables predictive analysis and the identification of patterns associated with defects and anomalies; Automation Technologies make it possible to implement rapid and automated corrective actions; and Digital Twin supports the virtual simulation of processes and the preventive evaluation of alternative scenarios. Considered jointly, these technologies represent the main informational and decision-making functions through which digitalization can contribute to quality improvement.

Table 6. Industry 4.0 Technologies and Their Relevance for Quality Management

Industry 4.0 Technology	General role	Relevance for Quality Management	Reason for selection in the thesis
<i>IoT / IIoT</i>	Data collection from machines, sensors, and products	Real-time monitoring, anomaly detection, traceability	<i>Primary technology for acquiring quality data from the process</i>
<i>ML/ AI</i>	Predictive analysis and pattern recognition	Defect prediction, predictive quality, predictive maintenance	<i>Primary technology for transforming data into predictive capability</i>
<i>Automation Technologies</i>	Automatic execution of operational and corrective actions	Automatic process adjustment, rapid response, error reduction	<i>Primary technology for reducing intervention times and automating corrective actions in quality processes</i>
<i>Digital Twin</i>	Virtual representation and simulation of the physical system	Virtual testing, process simulation, fault anticipation	<i>Primary technology for simulating scenarios and preventing defects</i>

MES	Operational integration among production, quality, and management	Traceability, process control, shop-floor coordination	<i>Primary technology for linking operational data and managerial decisions</i>
Cloud Computing	Storage and scalability	Infrastructural support for quality data	<i>Complementary technology, not the focus</i>
Cybersecurity	Protection of data and systems	Reliability and integrity of information	<i>Enabling condition, treated as a cross-cutting requirement</i>
Additive Manufacturing	Additive production	Impact on design and specific processes	<i>Relevant but sector-specific, less central for generalizable CoPQ analysis</i>
AR/VR	Visual support and training	Training, maintenance, assistance	<i>Complementary to quality processes</i>
Robotics/Cobots	Physical automation and human-machine collaboration	Reduction of human error, repeatability, operational stability	<i>Relevant technology, but considered a subcategory of Automation Technologies in the proposed framework</i>
Blockchain	Secure and distributed recording	Extended traceability along the supply chain	<i>Relevant for specific cases, less central within the scope of the thesis</i>

Note: Compiled by the author based on the literature review.

Table 6 summarizes the role of the main Industry 4.0 technologies, their relevance for Quality Management, and the reasons that guided the selection adopted in this research.

Other Industry 4.0 technologies, such as Cloud Computing, Cybersecurity, Additive Manufacturing, Augmented Reality, Virtual Reality, Blockchain, and Robotics, play an important role in digital manufacturing systems. However, in the context of this thesis they are considered primarily as complementary or infrastructural technologies, since their contribution to CoPQ reduction is more indirect than that of the selected technologies.

In summary, Industry 4.0 constitutes the technological paradigm within which quality management is transformed into an increasingly data-driven, interconnected, and predictive practice. Although the paradigm includes a broad set of technologies, this thesis focuses on IoT, ML/AI, Automation Technologies, Digital Twin, and MES, as these technologies are more directly linked to data collection,

operational integration, predictive analysis, and process simulation. This selection makes it possible to analyze in a targeted manner the contribution of digital technologies to quality management and to the reduction of the CoPQ in manufacturing systems.

2.1.1 Internet of Things (IoT) in manufacturing

The Internet of Things (IoT) represents one of the fundamental technologies of the Industry 4.0 paradigm, because it makes it possible to connect machines, sensors, products, and information systems through digital networks capable of collecting and exchanging data continuously. In the manufacturing context, IoT transforms production resources that were traditionally isolated into connected and monitorable entities, creating the conditions for data-based process management and greater visibility of operations (Atzori et al., 2010; Xu et al., 2018).

The basic idea behind IoT is that physical objects can be equipped with their own digital identity and can communicate information related to their status, location, or operating conditions. In industrial environments, this evolution has led to the development of the Industrial Internet of Things (IIoT), an expression used to indicate the application of IoT to production processes, industrial infrastructures, and cyber-physical systems (Atzori et al., 2010; Lee et al., 2015).

In the manufacturing context, IoT performs a particularly relevant function because it enables the transition from production processes monitored discontinuously to processes observable in real time. In traditional systems, quality information is often collected through periodic inspections, sampling, or manual records. By contrast, IoT enables the continuous collection of data directly from the production process, reducing the delay between the occurrence of a deviation and its identification. This capability for continuous observation constitutes one of the fundamental prerequisites of Quality 4.0, because it makes it possible to transform quality control from a retrospective activity into a dynamic and data-driven process (Sony et al., 2020; Salimbeni et al., 2023).

The applications of IoT in manufacturing are numerous. A first area concerns real-time process monitoring, in which sensors and connected devices make it possible to continuously observe the state of machines and production processes. Such monitoring makes it possible to identify deviations from expected operating conditions and to support timely interventions before the deviation translates into product defects or nonconformities.

A second area concerns predictive maintenance, in which data collected by sensors are used to monitor equipment condition and predict potential failures. The reduction of unexpected breakdowns contributes indirectly to quality improvement, since unstable or degraded machines can generate process variations, defects, scrap, and rework (Lee et al., 2015; Kalsoom et al., 2021).

A third application area concerns traceability. Through IoT devices, identification codes, sensors, and localization systems, it becomes possible to trace materials, semi-finished products, finished products, and operating conditions along the different phases of the production process. This capability is particularly relevant in sectors where conformity, traceability, and process documentation represent fundamental requirements. IoT-supported traceability makes it possible not only to reconstruct the production history of a component, but also to link any nonconformities to the process conditions that generated them (Baran & Korkusuz Polat, 2022).

From the point of view of Quality Management, the most relevant contribution of IoT lies in the development of observability, understood as the organization's ability to understand in real time what is happening within the production system. Greater observability makes it possible to reduce operational uncertainty, identify anomalies, detect process deviations, and support more timely and effective decisions. For this reason, IoT can be considered a primary enabling technology, because it provides the informational basis necessary for the functioning of other Industry 4.0 technologies, including Machine Learning, Digital Twin, MES, and advanced automation systems (Frank et al., 2019; Salimbeni et al., 2023).

From the standpoint of the CoPQ, IoT can contribute to the reduction of CoPQ through different mechanisms. The timely detection of anomalies can limit scrap, rework, and production stoppages, thereby reducing Internal Failure Costs. Greater traceability can facilitate the management of nonconformities and limit the impact of External Failure Costs. In addition, the availability of continuous data can increase the efficiency of control activities, allowing some checks to be integrated directly within the production process. However, these benefits depend on the organization's ability to effectively integrate the collected data into decision-making processes and quality management systems.

Despite its potential, the implementation of IoT in manufacturing contexts presents some critical issues. The first concerns integration with legacy systems, which are often not designed to communicate with modern digital platforms. The second concerns the quality of the data collected: incomplete, non-standardized data or data lacking adequate operational context can limit the possibility of generating useful information for quality improvement. The third critical issue concerns cybersecurity, because increased connectivity exposes machines, systems, and production data to new cyber risks. Finally, the adoption of IoT requires adequate technical and organizational competencies, since the availability of sensors and data does not automatically guarantee analytical capability, organizational learning, or quality improvement (Xu et al., 2018; Sony et al., 2020).

In summary, IoT constitutes a fundamental technology for the digital transformation of quality in manufacturing systems. Its main contribution does not lie simply in device connectivity, but in the

ability to make production processes observable, providing continuous and contextualized data that support real-time monitoring, traceability, early anomaly identification, and integration with advanced analytical and decision-making systems. From this perspective, observability represents the principal operational capability enabled by IoT and the mechanism through which this technology can contribute to quality improvement and to the reduction of CoPQ.

2.1.2 Machine Learning and AI for quality prediction

Artificial Intelligence (AI) and Machine Learning (ML) represent some of the most transformative technologies associated with the Industry 4.0 paradigm, thanks to their ability to extract knowledge from data and support increasingly autonomous and predictive decision-making processes. Although the concept of AI dates to the mid-twentieth century, its large-scale application in manufacturing contexts has become possible only in recent years as a result of greater computational power, the diffusion of digital technologies, and the growing availability of data generated by production processes. In this scenario, AI and ML have become fundamental tools for transforming large volumes of operational data into useful information for improving industrial performance and quality (Jordan & Mitchell, 2015; Russell & Norvig, 2021).

Although the two terms are often used as synonyms, ML is in fact a specific subset of AI. Whereas AI encompasses the broad set of techniques aimed at simulating cognitive capabilities typically associated with human intelligence, ML focuses on the development of algorithms capable of learning automatically from data and improving their performance without being explicitly programmed for every possible situation. Through the analysis of historical data, these algorithms can identify relationships, recognize patterns, classify events, and generate predictions regarding the future behavior of the observed systems (Jordan & Mitchell, 2015).

In the manufacturing context, the value of ML derives primarily from its ability to analyze complex phenomena characterized by numerous interdependent variables and nonlinear relationships. Modern production systems generate enormous amounts of data from sensors, machines, automation systems, MES platforms, and IoT devices. Many of the relationships that influence product quality are difficult to identify through traditional statistical analysis methods, especially when they involve numerous variables interacting simultaneously. ML algorithms, by contrast, make it possible to identify hidden correlations and recurring patterns that can be used to better understand the behavior of production processes and support more effective decisions (Wuest et al., 2016).

The growing integration of IoT and ML has further expanded the range of possible applications for these technologies. If IoT helps make the production system observable through the continuous collection of data, ML provides the tools needed to interpret that information and transform it into

operational knowledge. In this sense, the two technologies perform complementary roles: IoT enables observability, while ML enables predictability, that is, the ability to anticipate the future evolution of processes based on the available data (Frank et al., 2019).

The industrial applications of Artificial Intelligence and ML are numerous and involve different aspects of operations management. One of the most developed areas concerns predictive maintenance, in which predictive algorithms are used to monitor equipment condition and estimate the probability of future failures. Through the analysis of parameters such as vibrations, temperatures, energy consumption, and operational performance, it is possible to identify early signals of degradation and schedule maintenance interventions before unplanned stoppages occur. This approach makes it possible to increase equipment reliability and reduce production interruptions, with positive effects also on the quality of the products manufactured (Lee et al., 2018).

Particularly relevant to this research, however, is the contribution of ML to quality prediction processes. In traditional quality control systems, product conformity is generally verified through inspection activities performed after production or during specific phases of the process. Although such approaches make it possible to identify nonconformities, they intervene only after the defect has already appeared. By contrast, ML algorithms make it possible to estimate the probability of future defects based on the operating conditions observed during the production process. Through the analysis of historical data relating to processing parameters, environmental conditions, machine performance, and quality outcomes, predictive models can identify operating configurations associated with a greater probability of generating nonconformities, enabling preventive interventions before the problem materializes (Wuest et al., 2016).

This ability to anticipate future events represents one of the most significant changes introduced by digital technologies in quality management. Whereas traditional Quality Management models have historically been oriented toward identifying and correcting defects, the availability of predictive tools makes it possible to shift attention progressively toward the prevention of the causes that generate such defects. In this way, quality is no longer interpreted exclusively as the ability to control the outcome of the process, but as the ability to understand and govern the mechanisms that determine that outcome (Sony et al., 2020).

The literature devoted to Quality 4.0 considers ML one of the technologies most responsible for the transition toward data-driven quality systems. The possibility of processing large volumes of data and generating reliable predictions makes it possible to support evidence-based operational decisions, reduce uncertainty, and improve the timeliness of interventions. Moreover, the ability to identify patterns that are difficult to observe through conventional techniques helps increase process understanding and continuously improve the organization's quality performance (Antony et al., 2022).

From an economic perspective, ML can directly influence different components of the CoPQ. The early prediction of anomalies and defects helps reduce Internal Failure Costs by limiting the generation of scrap, rework, and production stoppages. Similarly, the ability to identify high-risk situations in a timely manner is expected to reduce the probability that nonconforming products will reach the final customer, thereby helping contain the External Failure Costs associated with complaints, returns, and warranty interventions. Greater predictive accuracy can also improve the efficiency of quality control activities by optimizing the allocation of resources devoted to inspection and product verification (Farooq et al., 2017).

Despite its potential, ML presents some limitations. The reliability of predictions depends strongly on the quality of the data used during the training phase, the representativeness of the available data, and the ability to update the models periodically in response to changes in operating conditions. In addition, the growing complexity of some algorithms, particularly those based on Deep Learning techniques, can make it difficult to interpret the process through which a given prediction is generated, raising issues related to transparency and trust in automated decisions (LeCun et al., 2015).

In summary, the most relevant contribution of ML to quality management lies in its ability to transform operational data into predictive knowledge. If IoT makes production processes observable through the continuous collection of information, ML makes it possible to use that information to anticipate future behavior, identify risk conditions, and support preventive interventions. For this reason, ML can be considered the primary enabler of predictability, that is, the organizational ability to foresee future events and intervene before nonconformities appear. This capability constitutes one of the central elements of Quality 4.0 and constitutes a fundamental step toward understanding how digitalization can contribute to the reduction of the CoPQ in manufacturing systems.

2.1.3 Digital Twin technology and virtual simulation

The concept of the Digital Twin represents one of the most significant developments introduced by the Industry 4.0 paradigm, as it makes it possible to create a dynamic digital representation of a physical system and keep it continuously updated through data coming from the real world. In general terms, a Digital Twin can be defined as a digital replica of an object, a process, or a production system, capable of receiving real-time operational data and reproducing its behavior in a virtual environment. Unlike traditional simulation models, which are used statically and independently of the physical system, the Digital Twin maintains a continuous connection with the real system through data flows that constantly update its operating state (Tao et al., 2019).

The operation of a Digital Twin is based on the integration of the physical system, the virtual model, and the data generated during production operations. Sensors, IoT devices, and information systems

collect information related to the operating conditions of the real system, while mathematical models and processing tools continuously update digital representation. In this way, Digital Twin does not merely describe the physical system, but reflects its evolution over time, making it possible to monitor its performance and support the analysis of different operating scenarios (Negri et al., 2017).

The growing interest in this technology derives from its ability to overcome one of the main limitations of traditional production systems: the difficulty of evaluating the effects of operational changes without intervening directly in the real process. In manufacturing contexts, any change in production parameters, machine configuration, or the sequence of operations can generate costs, interruptions, or risks for product quality. The Digital Twin, by contrast, makes it possible to analyze different operating configurations virtually before their physical implementation, reducing the uncertainty associated with decisions and improving the organization's ability to identify more effective solutions (Kritzinger et al., 2018).

Digital Twin applications in manufacturing include process design, production monitoring, predictive maintenance, operational performance optimization, and quality management. In particular, the possibility of virtually reproducing the behavior of production systems makes this technology especially relevant in contexts characterized by high complexity and operational variability. Through the simulation of different process configurations, the Digital Twin makes it possible to evaluate in advance the impact of specific decisions on production and quality performance (Tao et al., 2018).

In the context of Quality Management, Digital Twin assumes strategic relevance because it makes it possible to analyze virtually the conditions that may generate defects and nonconformities. Whereas traditional quality control systems identify problems once they have already occurred, and predictive approaches based on ML estimate the probability that an event will occur, the Digital Twin adds the possibility of simulating alternative scenarios and evaluating in advance the effects of different operational decisions. This capability significantly expands the potential of prevention because it makes it possible to explore process configurations virtually and identify those strongly associated with the achievement of quality objectives (Tao et al., 2019).

The literature on Quality 4.0 and Zero-Defect Manufacturing (ZDM) highlights how the Digital Twin can contribute to the reduction of process variability through the early identification of potentially problematic operating conditions. The combination of real-time data, virtual models, and simulation capabilities makes it possible to evaluate alternative scenarios and identify possible critical issues before they produce significant effects on product quality (Psarommatis et al., 2020).

From an economic perspective, this capability can have a direct impact on reducing the CoPQ. The possibility of identifying and correcting process problems virtually helps reduce Internal Failure Costs

by limiting the production of scrap, rework, and operational inefficiencies. Similarly, the greater ability to prevent defects can help reduce External Failure Costs by decreasing the probability that nonconforming products will reach the final customer. In addition, virtual simulation makes it possible to evaluate different improvement strategies without immediately incurring the costs associated with their physical implementation, thereby promoting a more efficient management of the resources devoted to quality (Tao et al., 2019).

The effectiveness of the Digital Twin, however, depends on the quality of the available data and on the level of integration with the other Industry 4.0 technologies. An accurate virtual model in fact requires updated information coming from IoT systems, advanced analytical capabilities, and systems able to integrate and contextualize the data collected during production operations. For this reason, Digital Twin is frequently described in the literature as a technology strongly dependent on interaction with IoT, ML, AI, and digital integration systems such as MES (Kritzinger et al., 2018).

In summary, the main contribution of Digital Twin to quality management consists in creating a virtual simulation environment in which the behavior of production processes can be observed, understood, and improved before decisions are implemented in the real system. If IoT enables *observability* and ML enables *predictability*, Digital Twin enables Operational-Design Integration, that is, the organizational capability to simulate alternative scenarios, evaluate the effects of operational decisions, and optimize processes before their physical implementation. This capability represents a distinctive element of Quality 4.0 and constitutes an important mechanism through which digitalization can contribute to reducing variability, preventing defects, and decreasing the CoPQ in manufacturing systems.

2.1.4 Automation technologies and autonomous quality intervention

Automation constitutes one of the fundamental elements of modern industrial evolution and constitutes one of the technologies most strongly associated with the digital transformation of production systems. Although the concept of automation has been present in industry since the third industrial revolution, characterized by the diffusion of programmable controllers, numerical control systems, and automated production lines, the Industry 4.0 paradigm has significantly expanded the role of automation, transforming it from the simple automatic execution of repetitive activities into a dynamic capability for data-based adaptation and response (Xu et al., 2018).

In traditional industrial systems, automation was generally limited to the execution of predefined operations according to rigidly programmed logics. Machines were able to perform repetitive activities with high levels of precision and speed but had limited capability to adapt to variations in operating conditions or unforeseen events. The emergence of Industry 4.0 has progressively modified this scenario through the integration of sensors, cyber-physical systems, industrial communication platforms, and

advanced analytics technologies, enabling the development of increasingly intelligent and responsive automated systems (Lee et al., 2015).

In the contemporary manufacturing context, automation can be defined as the set of technologies and systems that enable the automatic execution of operational, decisional, or corrective activities based on information generated by the production process. This definition includes not only industrial robots and automatic machines, but also adaptive control systems, algorithms for the automatic adjustment of process parameters, automated inspection systems, and mechanisms for autonomous response to events detected during production (Tao et al., 2018).

The evolution toward forms of intelligent automation has been fostered by the growing availability of data generated by digital systems and by integration with technologies such as IoT and Machine Learning. In this context, automated systems can react to operational variations, adapt their operating parameters, and implement corrective actions without requiring direct operator intervention. The combination of process observation, data analysis, and automatic intervention capability constitutes one of the distinctive elements of modern intelligent production systems (Sony et al., 2020).

Applications of automation in manufacturing include automatic process control, adaptive machine adjustment, automated quality inspection, material handling, and the execution of corrective actions in response to events identified during production. Automation assumes a relevant role in quality processes when it makes it possible to reduce the time elapsed between the identification of an anomaly and the implementation of the response needed to correct it (Psarommatis et al., 2020).

One of the most significant developments introduced by Industry 4.0 concerns the diffusion of closed-loop quality control systems, in which the information collected during the production process is used to modify operating conditions automatically. In such systems, deviations are detected, analyzed, and corrected through a continuous flow of monitoring and intervention that makes it possible to keep the process within acceptable limits. This approach is expected to reduce reaction times and limits the propagation of nonconformities along the production system (Tao et al., 2018).

In the field of Quality Management, automation also contributes to the development of the Zero-Defect Manufacturing (ZDM) paradigm. This approach is based on the ability to identify, predict, and promptly correct the conditions that could compromise product quality. In this context, automation performs an essential function because it makes it possible to transform the information generated by digital systems into concrete and immediate operational interventions (Psarommatis et al., 2020).

A concrete example of this predictive orientation is offered by Verna et al. (2023), who develops a self-adaptive defect prediction model based on the structural complexity of the assembled product. Unlike static prediction models that require a full historical dataset before deployment, this self-adaptive

approach updates its predictions progressively as new production data becomes available, allowing the model to remain accurate even under changing operating conditions or evolving product configurations. This adaptive capability is particularly relevant for automated quality control systems, since it supports real-time decision-making without requiring the collection of an extensive defect history before the model becomes operationally useful.

The relevance of automation for quality management derives primarily from its ability to reduce the delay between the identification of a deviation and the implementation of the corresponding corrective action. In traditional systems, the decision-making process often requires a sequence composed of problem detection, analysis, communication, and intervention. Each of these phases introduces delays that may increase the number of nonconforming products generated before the problem is corrected. Automation, by contrast, helps compress this time interval, favoring faster, more consistent, and more reliable interventions (Sony et al., 2020).

From an economic perspective, this capability can directly influence the CoPQ. The reduction of response times makes it possible to limit the quantity of defective products generated during uncontrolled process events, thereby contributing to the decrease in Internal Failure Costs associated with scrap, rework, and production losses. Similarly, a greater capability to contain nonconformities is expected to reduce the risk that defective products will reach the final customer, helping to limit the External Failure Costs linked to complaints, returns, and warranty interventions (Farooq et al., 2017).

The effectiveness of automation technologies, however, depends on their integration with the other Industry 4.0 technologies. An automated system can intervene effectively only if it has reliable information on the state of the process, analytical capabilities able to interpret that information, and coordination mechanisms that enable the dissemination of decisions throughout the organization. For this reason, literature considers automation to be a technology complementary to IoT, Machine Learning, Digital Twin, and MES systems, which respectively provide observability, predictive capabilities, simulation, and operational integration (Lee et al., 2015; Tao et al., 2018).

In the context of the present research, the main contribution of Automation Technologies lies in the ability to transform information and predictions into timely operational actions. If IoT makes production processes observable, ML makes their behavior predictable, and Digital Twin makes it possible to simulate alternative scenarios, automation enables the rapid implementation of the corrective actions needed to keep the process within desired operating conditions. For this reason, it can be interpreted as the primary enabler of rapid response, that is, the organizational capability to react promptly to anomalies and prevent the propagation of defects. This capability represents an essential element of Quality 4.0 and is expected to contribute to the reduction of variability, the improvement of quality performance, and the containment of CoPQ in manufacturing systems.

2.1.5 Manufacturing Execution Systems (MES) and integration

MES represent one of the most important technologies of Industry 4.0 because they perform a linking function between the operational level of production and the managerial level of the organization. Unlike other digital technologies focused primarily on data collection, predictive analysis, or simulation, MES are characterized by their ability to integrate information from different business systems and make it available in real time to support production operations. In this sense, they constitute a fundamental element for ensuring information consistency, operational coordination, and process visibility within modern digitalized manufacturing systems (Kletti, 2007).

The development of MES can be interpreted as a response to the growing complexity of production systems and to the need to reduce information fragmentation across departments, processes, and decision-making levels. In contemporary manufacturing contexts, data related to production, quality, maintenance, and planning must be collected, organized, and shared consistently to support effective and timely decisions. MES make it possible to overcome these information barriers by creating an integrated environment for operations management (Saenz de Ugarte et al., 2009).

From a functional standpoint, a Manufacturing Execution System can be defined as an information system capable of monitoring, controlling, and documenting the execution of production activities throughout the entire production cycle. According to the ISA-95 model, MES occupies an intermediate position between enterprise planning systems and field-level automation systems, enabling the continuous flow of information between the strategic and operational levels (ISA, 2010).

The importance of MES within the Industry 4.0 paradigm derives primarily from their ability to integrate data from heterogeneous sources and contextualize them within production processes. Information generated by monitoring, quality, maintenance, and production systems can be connected within a single information infrastructure, making it possible to achieve a more complete understanding of manufacturing operations and their performance (Kletti, 2007).

In the manufacturing context, MES applications include production order management, monitoring of operational performance, control of production resources, automatic collection of process data, and support for quality activities. However, one of the most relevant aspects for this research concerns the ability to ensure traceability throughout the entire production process. Through the systematic recording of operational events, process conditions, and product characteristics, MES make it possible to reconstruct in detail the production history of a component or a batch, facilitating the identification of the causes of nonconformities and the containment of quality problems (Saenz de Ugarte et al., 2009).

Traceability represents an essential component of quality management in modern manufacturing systems. In the absence of reliable information on the conditions that characterize the production

process, it is difficult to identify the causes of a defect, implement effective corrective actions, and prevent the recurrence of similar problems. MES contributes to reducing this uncertainty through the creation of a structured archive of operational information, making it possible to connect production events and quality outcomes (Demartini & Tonelli, 2018).

In the context of Quality 4.0, this integration capability assumes particularly significant relevance. The data collected by IoT systems, the predictions generated by ML algorithms, the simulations developed through Digital Twins, and the information coming from automation systems produce value only if they can be shared, contextualized, and used throughout the entire production system. In this scenario, MES act as an integrating element among the different digital technologies, contributing to the construction of a coordinated ecosystem for quality management (Demartini & Tonelli, 2018).

From an economic perspective, the coordination capability offered by MES can directly influence different components of the CoPQ. Greater traceability facilitates the identification of the causes of defects and can reduce the time required to implement corrective actions, thereby contributing to the decrease in Internal Failure Costs. Similarly, the availability of detailed information on production processes makes it possible to contain nonconformities more effectively before they reach the final customer, is expected to reduce External Failure Costs. In addition, the automation of information collection and management can improve the efficiency of quality control activities by optimizing the use of resources dedicated to inspections and documentation.

The implementation of an MES is not, however, without challenges. Integration with legacy systems, data standardization, compatibility among different software platforms, and the management of organizational change represent some of the main obstacles identified in the literature. In addition, the effectiveness of an MES depends strongly on the quality of the available information and on the organization's ability to use such information in daily decision-making processes. Consequently, the success of an MES project requires not only technological investments, but also adequate organizational capabilities and a clear digital integration strategy (Saenz de Ugarte et al., 2009).

In the context of the present research, the main contribution of MES lies in their ability to integrate and coordinate information coming from the different levels of the production system. If IoT makes processes observable, ML makes their behavior predictable, the Digital Twin makes it possible to simulate alternative scenarios, and automation enables rapid corrective interventions, MES ensure that all this information can be shared, contextualized, and used consistently throughout the organization. For this reason, they can be interpreted as the primary enabler of coordination, that is, the organizational capability to connect data, processes, people, and technologies within an integrated quality management system. This capability represents one of the fundamental elements of Quality 4.0 and constitutes a necessary condition for transforming the potential of digital technologies into concrete improvements

in quality performance and in the reduction of CoPQ.

2.2. Quality 4.0: Data-driven quality management

The emergence of Industry 4.0 technologies has transformed the way organizations collect, process, and use information related to production processes. In this context, the concept of Quality 4.0 has developed and is defined as the application of Industry 4.0 technologies to the principles and practices of Quality Management to improve process control, defect prevention, decision support, and continuous improvement (Radziwill, 2018; Sony et al., 2020).

Unlike traditional models, which are based primarily on inspection activities, periodic audits, and retrospective performance analyses, Quality 4.0 introduces a data-driven approach to quality management. Decisions are supported by information generated continuously during production operations, enabling a deeper understanding of processes and faster identification of deviations. The availability of data from sensors, machines, MES systems, and digital platforms therefore makes it possible to manage quality in a more dynamic, adaptive, and proactive manner (Antony et al., 2022).

The literature highlights that Quality 4.0 does not replace the traditional principles of Quality Management but rather represents an evolution of them. Concepts such as continuous improvement, defect prevention, customer orientation, and variability reduction retain their theoretical validity, while the integration of IoT, Machine Learning, Digital Twin, Automation Technologies, and MES expands organizations' capacity to monitor processes, anticipate anomalies, simulate alternative scenarios, and coordinate information from different business functions (Carvalho et al., 2021; Salimbeni et al., 2023).

The importance of this evolution is particularly evident in the manufacturing sector, which is characterized by increasing product complexity, greater production customization, and increasingly integrated supply chains. In this context, the availability of up-to-date information and the ability to interpret it promptly are essential factors for maintaining competitiveness and reducing CoPQ (Antony et al., 2022). Quality 4.0 can therefore be interpreted as an integrated system of operational capabilities enabled by digital technologies.

This evolution provides the theoretical basis for the specific capabilities analyzed in the following sections, relating to real-time monitoring, predictive capabilities, the Zero-Defect Manufacturing paradigm, and integrated quality management.

2.2.1 Real-time monitoring and automated defect detection

One of the most significant changes introduced by the digital transformation of quality concerns the ability to continuously observe the behavior of production processes and identify anomalies at the very

moment they occur. This evolution represents a break from traditional quality control models, historically based on periodic inspections, sample checks, and analyses carried out after production operations had already been completed. In such approaches, quality is assessed after the product has been manufactured or after the defect has already appeared (Montgomery, 2019).

The origin of this logic can be traced back to the first developments of Statistical Process Control (SPC), introduced by Shewhart in the 1920s. Although statistical process monitoring represented a fundamental advance over simple final-product inspection, even in the most advanced SPC systems control remained based on periodic measurements and discrete sampling. Decisions were therefore made based on data collected at defined intervals, creating a delay between the occurrence of a deviation and its identification (Montgomery, 2019).

The evolution of digital technologies has progressively modified this paradigm. The diffusion of smart sensors connected devices, cyber-physical systems, and data collection platforms has made it possible to continuously monitor operating conditions throughout the entire production process. In this context, the concept of real-time monitoring can be defined as the ability to acquire, process, and interpret operational information during the execution of production activities themselves, drastically reducing the time lag between the observation of a phenomenon and the availability of the information needed to understand it (Santos et al., 2021).

The relevance of this capability does not derive exclusively from the increase in the amount of data available, but from the transformation of the role of information within the decision-making process. In traditional models, quality information was often used to explain events that had already occurred. In digitalized contexts, by contrast, data are used to understand what is happening at the very moment the process is taking place. This change is expected to reduce operational uncertainty and make it possible to intervene before small deviations become significant nonconformities (Escobar et al., 2022).

The adoption of continuous monitoring systems has fostered the development of a new generation of quality management approaches, often described in literature as smart quality control or real-time quality management. In these systems, the information generated by the process is continuously compared with reference parameters, tolerance thresholds, and expected behavior models. Any significant deviation can be identified almost immediately, enabling operators or automated systems to react before the problem propagates along the production line (Carvalho et al., 2021).

Alongside the evolution of real-time monitoring, growing attention has been devoted to automated defect detection systems, which represent one of the most advanced applications of Quality 4.0. The objective of such systems is to automatically identify defects, anomalies, or nonconformities without requiring direct human intervention. This capability has been made possible by the convergence of

advanced sensing, computer vision technologies, ML algorithms, and high-performance processing systems (Zonta et al., 2020).

Among the most widespread applications are vision-based inspection systems. Through high-resolution industrial cameras and image-recognition algorithms, these systems can identify surface defects, dimensional variations, geometric imperfections, assembly errors, and aesthetic anomalies with particularly high levels of accuracy. In many industrial contexts, especially in the automotive, electronics, and semiconductor sectors, the performance of such systems is comparable to or even superior to that achievable through human visual inspection, particularly in the presence of high production volumes and especially demanding quality requirements (Kamble et al., 2023).

Automated systems also offer greater consistency and repeatability in inspection activities. Human operators may be influenced by factors such as fatigue, experience, environmental conditions, and interpretive subjectivity, whereas automated systems apply uniform criteria to all analyzed products, reducing variability in the inspection process and improving the overall reliability of quality control (Nguyen & Harrison, 2022).

In digitalized systems, quality control tends progressively to become a function embedded within production operations. Monitoring is integrated directly into operating activities and continuously accompanies the product transformation process, reducing the traditional separation between production and quality control (Salimbeni et al., 2023).

The economic implications of this evolution are particularly relevant in the context of the CoPQ. Numerous studies highlight that a significant share of CoPQ derives from the late discovery of defects. The more advanced the production process is at the moment nonconformity is identified, the higher the costs associated with correcting it generally become. The ability to identify anomalies and deviations rapidly therefore contributes to reducing the amount of scrap, rework, and operational losses, mainly affecting Internal Failure Costs. At the same time, greater effectiveness in detecting nonconformities is expected to reduce the probability that defective products will reach the final customer, thereby helping to limit the External Failure Costs associated with complaints, replacements, and warranty interventions (Farooq et al., 2017).

However, the most important contribution of real-time monitoring does not consist simply in identifying defects more quickly. Its true relevance lies in the ability to build a continuously updated representation of the state of the production system. This representation constitutes the informational basis needed for more advanced capabilities such as anomaly prediction, process simulation, decision automation, and the implementation of strategies oriented toward Zero Defect Manufacturing. In other words, continuous monitoring is not the endpoint of quality digitalization, but the foundation upon which all

the other capabilities of Quality 4.0 are built.

From this perspective, real-time monitoring and automated defect detection can be interpreted as the operational manifestation of the observability capability introduced in the previous section. They enable the organization to continuously observe the behavior of production processes, reduce operational uncertainty, and create the conditions necessary for an increasingly preventive, adaptive, and data-driven quality management approach. For this reason, these capabilities represent the first pillar of Quality 4.0 and constitute the starting point for the predictive and preventive capabilities that will be analyzed in the following section.

2.2.2 Predictive and preventive capabilities

The evolution of quality management toward increasingly digitalized models has progressively changed not only the ways in which organizations observe their production processes, but also their ability to anticipate future behavior. If real-time monitoring makes it possible to identify deviations and anomalies quickly, as they occur, predictive capabilities make it possible to estimate the probability that specific events will occur before they generate operational or quality-related consequences. In this sense, prediction represents one of the distinguishing elements of Quality 4.0 and one of the main factors that differentiate contemporary quality management systems from traditional models based primarily on inspection and retrospective control (Antony et al., 2022).

Historically, a large share of quality activities has been oriented toward detecting and correcting nonconformities once they have already occurred. Even the more advanced prevention approaches developed within Total Quality Management, Six Sigma, and continuous improvement systems frequently relied on the analysis of historical data and the identification of the causes of problems that had already taken place. Although these methodologies significantly contributed to the reduction of variability and the improvement of quality performance, they remain strongly dependent on accumulated experience and on the ability to interpret past events (Montgomery, 2019).

The growing availability of operational data and the integration of digital technologies have made a different approach possible. Through the continuous analysis of the information generated by production processes, organizations can identify early signals associated with the onset of future deviations and use such information to estimate system behavior before problems actually manifest themselves. This shift from simple observation to prediction constitutes one of the most relevant transformations introduced by Quality 4.0, because it is expected to significantly reduce the uncertainty associated with operations management (Sony et al., 2020).

The literature highlights that predictive capabilities can be applied to different aspects of production. One of the most widespread applications concerns predictive maintenance. Through the analysis of

operating parameters such as vibration, temperature, energy consumption, and machine behavior, it becomes possible to identify patterns associated with degradation conditions and estimate the probability of future failures. Although such applications are generally discussed within the field of predictive maintenance, they also have important implications for quality, because failures, operational instability, and equipment deterioration frequently represent one of the main sources of variability in production processes (Lee et al., 2018).

Particularly relevant in the context of the present research is the ability to predict the onset of defects and nonconformities. In traditional production systems, defects are generally identified through control activities performed after they have already been generated. In prediction-oriented systems, by contrast, the objective is to identify operating conditions associated with a higher probability of producing nonconforming results. This approach makes it possible to act on the causes before they translate into actual defects, thereby transforming the quality process from a corrective activity into a preventive mechanism (Wuest et al., 2016).

The growing diffusion of preventive capabilities has also modified the very concept of prevention. In traditional models, prevention was interpreted as the set of activities aimed at avoiding the recurrence of problems already observed in the past. In Quality 4.0, by contrast, prevention takes on a dynamic and continuous dimension, grounded in the ability to use data to identify in a timely manner operating conditions associated with possible future critical issues. This enables organizations to act not only on the known causes of nonconformities, but also on emerging conditions that have not yet become evident (Carvalho et al., 2021).

This transformation is particularly significant in manufacturing contexts characterized by high operational complexity. The increase in the number of process variables, the growing customization of products, and the integration of supply chains make it increasingly difficult to manually identify all the possible combinations of factors that may influence quality. Predictive capabilities make it possible to address this complexity through the simultaneous processing of large quantities of information and the identification of relationships that would be difficult to observe through conventional approaches (Escobar et al., 2022).

From a managerial perspective, the value of predictive capabilities does not lie exclusively in generating accurate predictions, but above all in the possibility of supporting more timely and effective decisions. Prediction acquires relevance only when it is used to guide preventive actions aimed at modifying the future behavior of the system. For this reason, the literature frequently emphasizes that predictive capability and preventive capability must be considered complementary and closely interconnected elements. A prediction that does not generate any corrective action produces limited value from an operational standpoint (Salimbeni et al., 2023).

The economic implications of this capability are particularly relevant in the context of the CoPQ. The possibility of identifying early conditions that could generate defects makes it possible to significantly reduce Internal Failure Costs by limiting the production of scrap, rework, and nonconforming products. At the same time, greater effectiveness in prevention helps reduce the risk that undetected defects will reach the final customer, with positive effects on lowering the External Failure Costs associated with returns, complaints, and warranty interventions. Several studies show, in fact, that the cost of correcting a problem increases progressively as it approaches the final customer, making it economically advantageous to intervene as early as possible along the production process (Farooq et al., 2017).

Predictive capabilities also assume a central role in the gradual transition toward quality models oriented toward defect prevention rather than simple defect detection. This orientation represents one of the fundamental principles of Quality 4.0 and constitutes the theoretical basis for more advanced paradigms such as ZDM, in which the objective is not to control the quality of the finished product, but to create operating conditions that minimize the very probability that a defect will be generated (Psarommatis et al., 2020).

From this perspective, predictive and preventive capabilities can be interpreted as the operational manifestation of the predictability capability introduced in the previous sections. If continuous monitoring provides visibility over the current state of the process, prediction makes it possible to extend that visibility into the future, enabling the organization to anticipate deviations and act before they produce undesirable consequences. This capability constitutes one of the main distinguishing elements of Quality 4.0 and constitutes the natural link between process observation and the advanced defect-prevention paradigms that will be analyzed in the following section devoted to Zero Defect Manufacturing.

2.2.3 Autonomous quality intervention and rapid response

The evolution of quality management toward digitalized models is not limited to the ability to observe processes in real time or to predict the occurrence of future anomalies. For these capabilities to produce an effective improvement in operational performance, the information generated must be transformed into corrective actions capable of modifying the behavior of the production system. In this sense, one of the most relevant contributions of Quality 4.0 lies in the development of mechanisms that enable increasingly rapid, coordinated, and, in some cases, fully autonomous interventions. The ability to respond promptly to operational deviations represents, in fact, the link between the knowledge generated by data and the concrete improvement of quality performance (Psarommatis et al., 2020).

In traditional quality management models, the response process to a nonconformity is characterized by a sequence of activities that include problem identification, communication of the event to the

responsible operators, cause analysis, and implementation of corrective actions. Although this approach makes it possible to address numerous quality-related issues effectively, it inevitably introduces delays that may favor the propagation of deviations along the production process. In many industrial contexts, the time required to identify, understand, and correct a deviation may in fact result in the production of additional nonconforming components, the accumulation of rework, or the interruption of operating activities (Montgomery, 2019).

The integration of digital technologies has progressively modified this paradigm by reducing the time that elapses between the detection of an anomaly and the implementation of the corrective response. Thanks to the availability of real-time updated information and the growing automation of decision-making processes, many organizations are now able to intervene on operating conditions almost immediately after a deviation is identified. This evolution has led to the development of closed-loop quality management systems, in which monitoring, analysis, and intervention are closely integrated within a single continuous operational cycle (Tao et al., 2018).

The smart manufacturing literature highlights how response speed represents a critical factor for maintaining quality in complex production systems. In environments characterized by high automation, high production volumes, and short cycle times, even apparently minimal deviations can generate significant consequences if they are not corrected promptly. The availability of rapid response mechanisms therefore makes it possible to limit the spread of anomalies and preserve the stability of the production process (Lee et al., 2015).

In this context, the concept of autonomous quality intervention emerges, which can be defined as the ability of a production system to implement corrective or preventive actions based on the information generated by its own monitoring and analysis mechanisms. Such interventions may take different forms, ranging from the automatic modification of process parameters to equipment adjustment, from the isolation of suspect batches to the automatic activation of procedures for containing nonconformities. The objective is not to eliminate the human role completely, but to reduce the delay between problem identification and solution implementation (Al Shahrani et al., 2023).

The growing diffusion of cyber-physical systems and intelligent industrial architecture has fostered the development of increasingly sophisticated self-regulation mechanisms. In such systems, the information collected by sensors is continuously compared with reference operating conditions; if a significant deviation is identified, the system can intervene directly to restore the desired conditions without waiting for an external intervention. This approach makes it possible to increase the resilience of production processes and reduce dependence on exclusively manual corrective activities (Lee et al., 2015).

From the perspective of quality management, the capability for autonomous intervention represents a

particularly significant change. Historically, quality control was conceived as a function oriented toward the identification and documentation of nonconformities. In digitalized systems, by contrast, the focus shifts progressively toward the ability to contain and correct deviations before they produce relevant effects. This entails a transformation in the very role of quality, which evolves from a verification activity to an active mechanism for regulating the production system (Carvalho et al., 2021).

The industrial applications of these capabilities are particularly evident in advanced production systems. For example, production lines equipped with automatic control systems can modify processing parameters when variations in operating conditions are detected. Similarly, machine-vision systems integrated with automation platforms can automatically stop the production flow in the presence of critical anomalies or segregate nonconforming components before they are transferred to subsequent stages of the process. In such contexts, quality depends not exclusively on the ability to identify the defect, but on the speed with which the system is able to react to its possible onset (Psarommatis et al., 2020).

The economic relevance of this capability is particularly evident in the context of CoPQ. Numerous studies show that the cost associated with deviation increases progressively as the problem propagates along with the production process. Intervening rapidly therefore makes it possible to limit the number of products involved, reduce rework, and contain operational losses. Response speed affects the reduction of Internal Failure Costs because it limits the generation of scraps and defects, and it is also expected to influence External Failure Costs by decreasing the probability that nonconforming products will reach the final customer (Farooq et al., 2017).

Capabilities for autonomous intervention also assume a central role in the gradual evolution toward production systems oriented toward prevention rather than correction. If real-time monitoring provides visibility over the current state of the process and predictive capabilities make it possible to anticipate anomalies, rapid intervention represents the mechanism through which such information is converted into concrete operational improvements. In the absence of an effective response, even the most advanced monitoring and prediction systems risk producing only limited managerial value.

From this perspective, autonomous quality intervention and rapid response can be interpreted as the operational manifestation of the Rapid Response capability enabled by digital technologies. They make it possible to reduce the time separating knowledge and action, transforming quality from a predominantly diagnostic function into a dynamic system of continuous adaptation. This capability reflects the third pillar of Quality 4.0 and constitutes the natural link between the predictive capabilities analyzed in the previous section and the Zero-Defect Manufacturing paradigm, which will be examined in the following section.

2.2.4 Zero Defect Manufacturing (ZDM) paradigm

The concept of Zero-Defect Manufacturing (ZDM) represents one of the most advanced evolutions of quality management in contemporary production systems. Although the idea of completely eliminating defects may appear ambitious, the ZDM paradigm should not be interpreted as the unrealistic goal of achieving absolute perfection, but rather as a systematic strategy oriented toward minimizing the probability of generating nonconformities through prevention, continuous monitoring, and timely intervention in production processes. In this sense, ZDM constitutes the most advanced expression of the transformation of quality from an inspection activity into a preventive and data-driven organizational capability (Psarommatis et al., 2020).

The theoretical roots of ZDM can be traced back to the earliest developments of the quality philosophy oriented toward prevention. As early as the 1960s, Crosby argued that quality should be interpreted as conformance to requirements and that the organizational objective should be to prevent defects rather than accept their inevitable presence. However, the technological limitations of the time made it extremely difficult to implement large-scale systematic prevention strategies. Most organizations still based quality management on control, inspection, and post-production correction activities (Crosby, 1979).

The diffusion of digital technologies has progressively changed this scenario. The integration of smart sensors, continuous monitoring systems, advanced analytics platforms, predictive models, and automation systems has made it possible to address the problem of defects in a radically different way than in the past. In this context, quality is no longer interpreted exclusively as the ability to identify nonconforming products, but as the ability to control the operating conditions that determine their generation. This change represents the fundamental principle underlying ZDM (Mayr et al., 2018).

The literature defines ZDM as an integrated set of methods, technologies, and strategies aimed at preventing the appearance of defects throughout the entire production cycle through continuous monitoring, anomaly prediction, and the implementation of timely corrective actions. Unlike traditional quality control systems, which intervene primarily on the product, ZDM focuses attention on process behavior and on the operating conditions that may generate nonconformities. The objective is not simply to reduce the number of observed defects, but to systematically control their causes (Psarommatis et al., 2020).

In this direction, Verna et al. (2021) proposes a probabilistic model for assessing quality control effectiveness from a Zero-Defect Manufacturing perspective. Their model quantifies how different combinations of inspection and monitoring configurations affect the probability of nonconforming products escaping detection, offering organizations a quantitative basis for evaluating and comparing

alternative quality control architectures against the ZDM objective. This probabilistic approach illustrates a broader trend within the ZDM literature: moving from a purely conceptual definition of zero defects toward operational models capable of estimating, in probabilistic terms, how close a given production system can realistically get to that goal.

One of the most relevant aspects of the ZDM paradigm is its strongly integrated nature. Defect prevention does not depend on a single technology or a specific control tool but emerges from the combination of different digital capabilities. Real-time monitoring enables continuous observation of the production process; predictive capabilities make it possible to identify early signals associated with the onset of future anomalies; autonomous quality intervention systems enable the rapid implementation of corrective actions; Digital Twins make it possible to simulate alternative scenarios and assess in advance the effects of operational decisions; and integration systems ensure the sharing of information among different business functions. ZDM can therefore be interpreted as the result of the convergence of all the capabilities analyzed in the previous sections.

From an operational standpoint, the ZDM paradigm is grounded in the progressive reduction of the time separating the onset of a potential deviation from its identification and management. In traditional models, this time interval may be long enough to allow the production of numerous nonconforming components before the problem is detected. In ZDM-oriented systems, by contrast, the objective is to create a continuous cycle of observation, learning, and intervention, limiting the propagation of anomalies and increasing the stability of production processes (Mayr et al., 2018).

A further distinctive element of ZDM concerns overcoming the traditional distinction between quality control and operations management. In conventional models, quality is frequently managed as a separate function responsible for verifying product conformity. In the Zero-Defect Manufacturing paradigm, by contrast, quality becomes an emergent property of the entire production system. Responsibility for defect prevention is distributed across the entire organization and integrated into daily decision-making processes, making quality an intrinsic element of operations management rather than an isolated specialist function (Bokrantz et al., 2020).

The economic implications of this approach are particularly relevant in the context of CoPQ. The literature highlights that a significant share of CoPQ derives from the need to correct problems that could have been avoided through earlier identification of the conditions that generated them. By reducing the probability of producing defective components, ZDM affects the reduction of Internal Failure Costs by limiting scrap, rework, material losses, and operational inefficiencies. At the same time, reducing the probability that nonconforming products reach the market makes it possible to contain External Failure Costs, often associated with warranty costs, recalls, complaints, and reputational damage (Farooq et al., 2017).

Numerous studies also highlight that the benefits of ZDM are not limited to defect reduction. More stable and controlled processes tend, in fact, to generate improvements also in terms of productivity, resource utilization, operational reliability, and customer satisfaction. In this sense, the paradigm should not be interpreted exclusively as a quality strategy, but as a broader approach aimed at the overall improvement of production system performance (Psarommatis et al., 2020).

However, the literature emphasizes that achieving the objectives associated with ZDM requires far more than the simple implementation of digital technologies. The availability of sensors, algorithms, and automated systems does not automatically guarantee defect prevention. The success of ZDM depends, in fact, on the organization's ability to integrate these tools into coherent decision-making processes, develop adequate analytical capabilities, and promote a culture oriented toward continuous improvement and organizational learning. In the absence of such conditions, technologies risk producing large quantities of data without generating any real improvement in quality performance (Bokrantz et al., 2020).

From this perspective, ZDM represents the synthesis of the main capabilities introduced by Quality 4.0. If real-time monitoring makes processes observable, predictive capabilities make it possible to anticipate possible anomalies, and rapid intervention systems enable them to be managed promptly, ZDM integrates these capabilities within a unified logic oriented toward the systematic prevention of defects. It therefore illustrates the transition from quality management as a control activity to quality as an organizational capability for learning, adaptation, and continuous improvement. For this reason, ZDM can be considered one of the paradigms most representative of Quality 4.0 and one of the main theoretical references for understanding how digitalization can contribute to the reduction of CoPQ in manufacturing systems.

2.2.5 Quality management as an integrated operational system

The evolution of quality toward the Quality 4.0 paradigm cannot be understood exclusively through the analysis of individual digital technologies or of the operational capabilities they make possible. Although continuous monitoring, predictive capabilities, rapid response, and ZDM paradigm represent fundamental elements of the digital transformation of quality, their value emerges fully only when these capabilities are coordinated within a coherent organizational system. In this sense, one of the main distinguishing characteristics of Quality 4.0 consists in the progressive transformation of quality management from a specialist function into an integrated operational system that extends across the entire organization.

Historically, quality has often been managed as a function separate from other business activities. Quality departments were generally responsible for inspection activities, conformity verification,

nonconformity management, and document control, while operational decisions relating to production, maintenance, or planning remained distributed among different organizational functions. Although this structure made it possible to develop important specialist expertise, it also frequently generated a separation between quality control and the day-to-day management of production operations (Juran & Godfrey, 1999).

The increase in the complexity of manufacturing systems has progressively highlighted the limits of this approach. Nonconformities rarely derive from a single isolated activity; rather, they emerge from interaction among multiple elements of the production system, including machines, operators, materials, procedures, suppliers, and decision-making processes. Consequently, quality improvement increasingly requires coordination among different business functions and the sharing of information from multiple sources (Antony et al., 2022).

Digital technologies have accelerated this transformation by making it possible to create stronger connections among previously separate processes. Data collected during production can be shared in real time with quality, maintenance, planning, and supply chain functions. In the same way, information relating to quality performance can be used to support operational decisions, maintenance strategies, production-capacity planning, and continuous improvement activities. In this context, quality progressively ceases to be an independent function and becomes an intrinsic component of the organization's operating system (Carvalho et al., 2021).

Quality 4.0 literature emphasizes that the true potential of digitalization does not lie in the simple automation of existing activities, but rather in the ability to create connections among processes, people, and information that were previously difficult to coordinate. The objective is not merely to collect more accurate data, but to build an informational ecosystem in which the knowledge generated by one business function can be immediately used by others. This fosters greater visibility of operations and makes it possible to address quality problems from a systemic rather than a localized perspective (Sony et al., 2020).

From this perspective, quality can be interpreted as an emergent property of the entire production system. Quality performance does not depend exclusively on the effectiveness of control activities, but on the organization's overall ability to coordinate resources, processes, and decisions toward shared objectives. This view is consistent with the systemic approach developed by Deming, according to which most quality problems derive from the characteristics of the system rather than from the individual performance of operators. Digital technologies now make it possible to apply this perspective concretely through systems in which information, processes, and decisions are continuously interconnected and updated (Deming, 1986).

The implications of this transformation are particularly relevant in the context of CoPQ. Many CoPQ arise from coordination problems, communication delays, lack of process visibility, and difficulties in identifying the causes of nonconformities. The integration of information flows and operating activities makes it possible to reduce such inefficiencies, improving the organization's ability to identify anomalies quickly, coordinate corrective actions, and prevent the recurrence of problems. Consequently, operational integration contributes not only to the reduction of Internal Failure Costs, but also to the improvement of the overall effectiveness of prevention and control activities.

A further distinctive element of Quality 4.0 concerns the progressive convergence among quality, operations, and business strategy. The availability of real-time information makes it possible to connect quality indicators directly to operational performance and to the organization's economic results. This connection fosters a more conscious management of the trade-offs among productivity, quality, reliability, and cost, enabling quality to be integrated into strategic decision-making processes rather than being limited to a support function.

In light of these considerations, Quality 4.0 can be interpreted as an integrated system of operational capabilities enabled by digital technologies. Continuous monitoring makes production processes observable; predictive capabilities make it possible to anticipate their future behavior; rapid intervention enables a prompt response to deviations; and the ZDM paradigm directs these capabilities toward the systematic prevention of nonconformities. However, it is the integration of these capabilities within a coordinated operating system that enables a sustainable improvement in quality performance.

From this perspective, quality management takes on the role of an organizational infrastructure that connects data, technologies, processes, and decisions within a single system oriented toward continuous improvement. This vision represents one of the fundamental principles of Quality 4.0 and constitutes the theoretical basis for the analysis of quality models adapted to digital contexts, which will be discussed in the following section.

2.3. Quality management models adapted to digital contexts

The emergence of Industry 4.0 technologies and the progressive diffusion of the Quality 4.0 paradigm have generated growing academic interest in the development of new models for quality management in digitalized contexts. Whereas traditional frameworks were built on limited data availability and reactive decision-making processes, digital transformation has introduced new possibilities for monitoring, analysis, and control that require a revision of existing interpretive paradigms (Radziwill, 2018; Sony et al., 2020).

This chapter critically analyzes these developments through three steps. First, it compares the main Quality 4.0 frameworks proposed in the literature, highlighting the differences between traditional and data-driven approaches to quality assessment. Second, it examines the relationship between operational quality and customer-perceived quality, showing how digitalization facilitates the integration of these two dimensions. Finally, it synthesizes the main theoretical implications that emerge for the development of the conceptual framework proposed in this research.

2.3.1 Traditional vs. data-driven quality frameworks: a comparative analysis

Quality assessment has always represented one of the fundamental activities of Quality Management. The ability to measure process performance, identify deviations, and monitor the achievement of quality standards is in fact the necessary prerequisite for any improvement initiative. However, the ways in which organizations collect, interpret, and use quality-related information have undergone profound transformations over the past decades. The emergence of Industry 4.0 technologies has not simply introduced new measurement tools but has changed the very way in which quality is observed, interpreted, and managed.

In traditional Quality Management models, quality assessment was based primarily on the periodic collection of data from inspection activities, audits, statistical controls, and documentary checks. Such information was generally analyzed through synthetic indicators, periodic reports, and statistical techniques aimed at identifying deviations from defined standards. For many years, this approach constituted the operational foundation of methodologies such as Statistical Process Control (SPC), TQM, and Six Sigma, contributing significantly to the improvement of production performance (Montgomery, 2019).

However, such systems were inevitably characterized by some structural limitations: data were often collected through sampling rather than complete observations, analyses were carried out periodically, and a large share of decisions was based on historical information. As a consequence, quality management remained predominantly oriented toward conformity verification and the identification of nonconformities that had already emerged.

The advent of Quality 4.0 has progressively modified this paradigm. The diffusion of smart sensors, IoT, Cyber-Physical Systems, AI, and Digital Twins has made it possible to continuously collect large volumes of operational data generated throughout the entire production system. Quality is no longer observed exclusively through periodic checks, but through continuous information flows that make it possible to monitor process behavior in real time and support more timely and informed decisions (Radziwill, 2018).

The difference between traditional and data-driven approaches concerns not only the quantity of data available, but above all the nature of the knowledge that can be generated. In traditional systems, quality assessment is mainly oriented toward describing performance that has already been observed; in data-driven systems, the analysis of information makes it possible to understand current process behavior, identify relationships among variables, and support increasingly preventive decisions. Attention therefore shifts from the simple measurement of conformity to the understanding of the mechanisms that determine quality performance (Antony et al., 2022).

This transformation is also reflected in the role of quality indicators. In traditional models, KPIs such as defect rate, scrap percentage, customer complaints, or process capability were used mainly to assess results that had already been achieved. In digitalized contexts, such indicators retain their relevance, but are progressively integrated with real-time information, predictive indicators, and advanced analytical tools capable of identifying early signals of possible critical issues. Quality management therefore becomes less oriented towards controlling the past and increasingly focused on prevention and continuous improvement.

The differences between the two approaches can be summarized in Table 7.

Table 7. Comparison between traditional and data-driven approaches to quality assessment

Dimension	Traditional approach	Data-driven approach
Data availability	<i>Periodic</i>	<i>Continuous</i>
Source of information	<i>Sampling and inspections</i>	<i>Sensors and digital systems</i>
Time horizon	<i>Retrospective</i>	<i>Continuous and prospective</i>
Focus of analysis	<i>Conformity</i>	<i>Process behavior</i>
Decision support	<i>Report-based</i>	<i>Based on real-time information</i>
Anomaly Management	<i>Defect identification</i>	<i>Early identification of deviations</i>
Predictive capabilities	<i>Limited</i>	<i>High</i>
Level of integration	<i>Functional</i>	<i>Systemic</i>

Note: Compiled by the author based on the literature review.

The emergence of this new paradigm has fostered the development of numerous theoretical frameworks aimed at explaining how digitalization is transforming quality management. However, literature does not converge toward a single shared interpretive model. On the contrary, Quality 4.0 frameworks tend to emphasize different aspects of the phenomenon.

The first category of studies interprets Quality 4.0 primarily as a technological phenomenon. From this

perspective, the transformation of quality is explained through the adoption of Industry 4.0 technologies and their application to production and control processes. For example, the studies by Baran and Korkusuz Polat (2022) and Carvalho et al. (2021) focus on identifying the technologies most relevant to improving quality performance, highlighting the role of IoT, Big Data Analytics, AI, and Cyber-Physical Systems. Although these contributions are particularly useful for understanding the technological landscape of Quality 4.0, they tend to focus more on the available tools than on the mechanisms through which these tools generate operational and organizational improvements.

A second stream of research focuses on the organizational and operational capabilities enabled by digitalization. In these models, technologies are considered relevant not so much because of their technical characteristics, but because of the new capabilities they enable organizations to develop. The studies by Sony et al. (2020) and Antony et al. (2022) highlight how the value of Quality 4.0 derives from the possibility of improving information collection, supporting decision-making, fostering organizational learning, and increasing organizational agility.

A third category of frameworks focuses on operational outcomes and defect prevention. This group includes studies devoted to ZDM, which interpret digitalization as a tool to reduce process variability, increase operational stability, and prevent the generation of nonconformities (Psarommatis et al., 2020).

To compare the main Quality 4.0 frameworks in the literature, Table 8 analyzes them with respect to the central dimensions of this research. It evaluates the degree of attention devoted to digital technologies, the operational capabilities they enable, the transformation of quality processes, quality performance, and CoPQ. This classification makes it possible to highlight not only the common elements among the different frameworks, but also the areas less developed in the literature. The frameworks are therefore compared according to their ability to explain the path linking digitalization to quality outcomes and the associated economic impacts. In the table, the symbol ✓ indicates that a given dimension is explicitly developed in the framework, “Partial” indicates that the dimension is mentioned but not systematically deepened, whereas X indicates that it is absent or marginal.

Table 8. Comparison of the main Quality 4.0 frameworks with respect to the dimensions analyzed in this research

Framework	Digital technologies	Operational capabilities	Transformation of quality processes	Quality performance	CoPQ
<i>Radziwill (2018)</i>	✓	Partial	Partial	✓	✗
<i>Sony et al. (2020)</i>	✓	Partial	Partial	✓	✗
<i>Carvalho et al. (2021)</i>	✓	Partial	Partial	✓	✗
<i>Antony et al. (2022)</i>	Partial	✓	✓	✓	✗
<i>Psarommatis et al. (2020)</i>	✓	✓	✓	✓	Partial
<i>Salimbeni et al. (2023)</i>	✓	✓	✗	✗	✗

Note: Compiled by the author based on the literature review.

The comparative analysis highlights several particularly significant elements of convergence. First, all frameworks recognize that the continuous availability of data represents the main distinguishing element of Quality 4.0 compared with traditional approaches. Second, broad consensus emerges regarding the role of digital technologies in supporting faster and more accurate decision-making processes. Finally, most authors agree that digital transformation should not be interpreted exclusively as a technological phenomenon, but also requires organizational, managerial, and cultural change.

Despite these convergences, some recurring limitations emerge. Technology-oriented frameworks describe the available technologies in detail but devote less attention to the operational capabilities they enable. Capability-oriented frameworks explain how digitalization transforms decision-making processes and organizational learning but often do not clarify through which technologies such capabilities are generated. Finally, operational frameworks focus primarily on outcomes in terms of quality and defect prevention without fully making explicit the causal path linking technologies, capabilities, and performance.

Consequently, literature frequently tends to treat the technological, organizational, and operational levels separately, without developing an integrated view capable of linking them systematically. Technologies are often described separately from the capabilities they generate, while quality performance is considered a final outcome without a clear explanation of the intermediate mechanisms that determine their improvement.

Particularly relevant to the present research is the observation that the economic dimension of quality remains relatively underdeveloped within Quality 4.0 literature. Although numerous studies recognize that digitalization can contribute to reducing defects, rework, and operational inefficiencies, few frameworks explicitly analyze the link between digital technologies and the reduction of the different categories of CoPQ. As a result, the relationship between digitalization, quality improvement, and economic impact continues to be treated more often implicitly than formally conceptualized.

This gap is particularly significant because it limits the understanding of the mechanisms through which digitalization generates economic value. Understanding that technology improves quality represents only part of the explanation; it is equally important to understand which operational capabilities are enabled by digital technologies, how such capabilities transform quality processes, and in what way these transformations contribute to the reduction of specific CoPQ categories.

In light of these considerations, an important research space emerges regarding the understanding of the mechanisms that link digital technologies, operational capabilities, the transformation of quality processes, and the reduction of CoPQ. The need to fill this gap reflects one of the main theoretical motivations of the present research and constitutes the conceptual foundation of the framework developed in the following chapters.

2.3.2 Integration of operational and customer-perceived quality

One of the most significant aspects of the evolution of quality management concerns the progressive overcoming of the traditional separation between operational quality and customer-perceived quality. For many years, these dimensions were analyzed as distinct phenomena: on the one hand, quality was assessed through technical indicators relating to the performance of production processes; on the other hand, customer satisfaction was interpreted as a commercial or marketing outcome. However, the growing attention to the value generated by quality and to the economic implications of nonconformities has highlighted the need to understand these dimensions as interconnected elements of a single system.

In the quality management literature, the concept of operational quality generally refers to the ability of a production process to generate products that conform to design specifications through stable, controlled, and repeatable performance. This dimension is traditionally measured using indicators such as defect rate, process capability, First Pass Yield, scrap levels, rework, and production reliability (Montgomery, 2019). Attention is therefore directed mainly toward the internal characteristics of the production system and its ability to satisfy technical and performance requirements.

At the same time, the literature on consumer behavior and service quality has developed the concept of customer-perceived quality, defined as the subjective evaluation that the customer makes regarding the ability of a product or service to satisfy their expectations. From this perspective, quality is not

determined exclusively by the technical characteristics of the product, but by the perception the customer develops during the usage experience. This approach has been widely developed in the studies of Garvin (1984), Kano et al. (1984), and Parasuraman et al. (1988), which highlighted how perceived quality represents a multidimensional construct influenced by technical, functional, and experiential factors.

Although these two perspectives have frequently been analyzed separately, a growing body of empirical evidence has shown that this distinction is artificial. Operational performance directly influences product performance and, consequently, customer experience. From this perspective, production defects do not simply represent internal technical problems for the organization but constitute events that can alter the value perceived by the customer. Reliability problems, premature failures, functional defects, or performance below expectations generate effects that extend beyond the production process, influencing customer satisfaction, corporate reputation, and the likelihood of future purchases. In this sense, operational nonconformities can be interpreted as the starting point of a causal chain linking production problems to economic and competitive outcomes (Rust et al., 1995).

The importance of this relationship emerges particularly clearly in the framework of CoPQ. The cost categories analyzed in Chapter 1 show that the economic consequences of quality problems are not limited to costs incurred inside the factory. Although scrap, rework, and operational inefficiencies represent significant components of Internal Failure Costs, a substantial share of the economic impact of poor quality is manifested through External Failure Costs, which include returns, warranty claims, complaints, product recalls, and loss of customer trust. These costs represent the main link between operational quality and perceived quality.

The growing diffusion of digital technologies has further strengthened this connection. In traditional production systems, feedback from the market was often characterized by significant delays and limited informational granularity. Organizations received information about customer satisfaction through complaints, periodic surveys, or aggregated sales data. By contrast, modern digital ecosystems make it possible to collect much more detailed and timely information about product use, in-service performance, and customer experiences. This allows internal operational events and market-perceived outcomes to be linked with greater precision (Antony et al., 2022).

The contemporary literature on Quality 4.0 suggests that one of the main advantages of digital technologies lies in the ability to integrate these different dimensions of quality within a single information system. Data originating from production, monitoring systems, post-sales service activities, and customer interactions can be connected to understand more accurately the relationships between the behavior of production processes and the value generated for the market. This makes it possible to overcome the traditional fragmented view of quality and to develop approaches more oriented toward

the integrated management of operational performance, customer satisfaction, and economic outcomes.

From this perspective, quality can be interpreted as a phenomenon that spans the entire value chain, linking the operational conditions of production processes to the perceptions developed by the final customer and, subsequently, to the economic impacts on the organization. This interpretation is particularly relevant to the present research, as it suggests that the reduction of the CoPQ should not be assessed exclusively through internal indicators of production efficiency, but also through the ability of organizations to improve the value perceived by the customer. The integration between operational quality and perceived quality therefore constitutes one of the most relevant theoretical contributions of Quality 4.0 and provides the necessary link between the operational performance analyzed in production systems and the economic impacts that motivate investments in digital technologies.

2.3.3 Synthesis and implications for the proposed framework

The analysis developed in the previous sections has shown that the digitalization of quality produces operational improvements through mechanisms that have not yet been systematically made explicit in literature. To address this gap, the present research adopts two complementary theoretical references: mechanistic explanation theory and the Dynamic Capabilities framework.

Mechanistic explanation

In the philosophy of the social sciences, a mechanistic explanation identifies the entities and intermediate activities that, when organized in a specific way, regularly produce a given outcome (Hedström & Ylikoski, 2010). Unlike correlational explanations, which merely document the association between variables, mechanistic explanations make explicit the causal pathway linking cause and effect.

Applied to the context of the present research, this approach implies that the relationship between Quality 4.0 technologies and the reduction of the CoPQ cannot be understood through the simple documentation of observed benefits. It is necessary to identify the intermediate processes, operational capabilities, and transformations of quality processes through which technologies produce their economic effects. This logic constitutes the architectural principle of the framework proposed in Chapter 4: technologies → operational capabilities → transformation of quality processes → CoPQ reduction.

Dynamic Capabilities as a theoretical foundation

The second theoretical pillar is provided by the Dynamic Capabilities framework (Teece, Pisano & Shuen, 1997; Teece, 2018). This framework argues that the value of technological resources does not

derive from their intrinsic characteristics, but from the organization's ability to integrate them, configure them, and reconfigure their competencies in response to changes in the operating environment. In this sense, digital technologies constitute resources that acquire organizational value only when they are incorporated into specific operational capabilities.

Teece (2018) articulates Dynamic Capabilities into three macro-processes: sensing (the ability to perceive opportunities and threats in the operating environment), seizing (the ability to act on identified opportunities through appropriate decisions and interventions), and reconfiguring (the ability to align and transform organizational structures in response to change). Helfat and Peteraf (2003) and Winter (2003) further distinguish between dynamic capabilities, which modify the configuration of resources, and operational capabilities, which enable the effective execution of current activities.

The five operational capabilities identified in this research represent the manifestation of Teece's dynamic capabilities within the specific context of digital quality management. The correspondence between the two frameworks is not accidental, but reflects a theoretical derivation: Observability and Predictability constitute the sensing dimension applied to production processes, since they enable the organization to perceive the current state of the system and anticipate its evolution; Rapid Response and Operational-Design Integration represent the seizing dimension, since they transform the knowledge generated by sensing into operational and decision-making interventions; Coordination, finally, corresponds to the reconfiguring dimension, since it reconfigures information flows and decision-making processes across organizational functions.

This derivation answers the question left open by existing literature: why these five capabilities and not others? The answer does not lie in a descriptive choice emerging from the literature review, but in a theoretical derivation from Teece's framework adapted to the context of Quality 4.0.

Implications for the framework in Chapter 4

The combination of mechanistic explanation and Dynamic Capabilities defines the theoretical premises of the proposed framework. First, the digital transformation of quality does not generate value through direct action of technologies on costs, but through the development of specific operational capabilities that transform quality management processes. Second, such capabilities do not operate as independent elements but as components of an integrated system corresponding to the sensing-seizing-reconfiguring cycle. Third, the Cost of Poor Quality constitutes the economic outcome variable through which the value of operational capabilities can be measured and compared.

These premises define the architecture of the framework developed in Chapter 4, in which the five operational capabilities are analyzed as intermediate mechanisms explaining the causal pathway between the adoption of Quality 4.0 technologies and the reduction of the different categories of CoPQ.

3. Methodological Approach

3.1. Introduction to the methodology and PRISMA protocol

This chapter describes the methodological approach adopted for the development of the proposed mechanistic framework. The research is configured as a theory-building study, whose objective is not the empirical measurement of the effects of Quality 4.0 technologies, but rather the development of an interpretive model capable of explaining the causal mechanisms through which such technologies contribute to the reduction of CoPQ in manufacturing systems.

To ensure methodological rigor and transparency in the process of identifying and selecting bibliographic sources, the research adopted the PRISMA 2020 protocol (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), originally introduced by Moher et al. (2009) and updated by Page et al. (2021). As highlighted by Page et al. (2021), PRISMA is based on two essential operational tools: a checklist composed of 27 items and a four-phase flow diagram that visually illustrates the path of information through the processes of identification, screening, eligibility assessment, and study inclusion.

A fundamental pillar of PRISMA 2020 is the clear distinction between the methodological conduct of the review and its reporting; whereas conduct concerns how the research is performed, PRISMA focuses exclusively on how it is described, starting from the assumption that transparent description is the only way to allow readers to evaluate the quality of the study. The adoption of this standard aims to ensure the reproducibility of the research by providing all the information necessary to judge the validity of the methods and the applicability of the results in one's own context. Compared with the original 2009 version, the 2020 protocol reflects the significant technological progress of the last decade, integrating specific guidance on the use of automation tools, natural language processing, and ML for evidence selection.

The adoption of the PRISMA 2020 protocol was motivated by the need to document the stages of bibliographic source selection in a structured and transparent way, reducing the risk of arbitrary selection and ensuring the traceability of every methodological decision. The following paragraphs describe the operational phases of the review process, from the definition of the search strategy to the structuring of the final corpus of 84 included studies.

3.2. Research objectives and theoretical assumptions

The framework is based on three fundamental theoretical premises. The first premise concerns the role of digital technologies in generating value: consistently with the literature on organizational capabilities, it is assumed that technologies do not produce economic benefits directly, but rather through the intermediate operational capabilities they make possible: observability, predictability, coordination, integration, and rapid response capability. The second premise concerns the process-based nature of quality improvement: the capabilities enabled by technologies produce economic effects only as far as they determine a transformation of existing quality processes. The third premise concerns the interpretation of CoPQ: in this research, CoPQ is considered not only as an economic indicator, but as the financial manifestation of operational inefficiencies associated with defects, rework, scrap, complaints, and other forms of organizational loss.

The framework follows a four-level logic: technologies influence operational capabilities → capabilities transform quality processes → transformations affect the economic categories of CoPQ.

Table 9 summarizes the correspondence between each research question, the methodological phase in which it is addressed, the data source used, and the expected output, ensuring coherence between the research questions, the method, and the results.

Table 9. Correspondence between Research Questions, Methodological Phase, Data Source, and Expected Output.

<i>Research Question</i>	<i>Methodological Phase</i>	<i>Data Source</i>	<i>Expected Output</i>
<i>RQ1: How does quality digitalization transform quality management processes in manufacturing systems?</i>	Analysis of quality process transformations	84 studies from the PRISMA systematic review (Scopus, Web of Science)	Mapping of the transformed process associated with each Quality 4.0 technology
<i>RQ2: Which operational capabilities are enabled by Quality 4.0 technologies, and what role do they play in the transformation of quality processes?</i>	Identification and definition of operational capabilities (framework development)	Cross-analysis of technology–capability associations reported in the reviewed studies	Definition of the five operational capabilities (Observability, Predictability, Rapid Response, Operational-Design Integration, Coordination)

<i>RQ3: How can Quality 4.0 technologies, through specific operational capabilities, contribute to the reduction of different categories of Cost of Poor Quality in manufacturing contexts?</i>	Causal synthesis linking capabilities to CoPQ categories	Evidence on capability–CoPQ relationships extracted from the reviewed literature	The proposed mechanistic framework (Technology → Capability → Process → CoPQ)
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Note: Compiled by the author based on the literature review.

3.3. Literature review strategy

The development of the mechanistic framework required the integration of evidence drawn from heterogeneous strands of literature: Quality 4.0, Industry 4.0, Cost of Quality (CoQ), Cost of Poor Quality (CoPQ), dynamic capabilities, digital manufacturing systems, and emerging technologies applied to quality management. The review strategy was structured to identify and integrate evidence useful for understanding the causal mechanisms that connect digital technologies to operational capabilities and to the reduction of CoPQ.

In line with the requirements of the PRISMA 2020 protocol, which requires the clear identification of every consulted database and the related access platform (Item 6, Page et al., 2021), the research was conducted primarily through the Scopus database, chosen for its broad bibliographic coverage in the fields of industrial engineering, management, and production systems. Scopus was preferred to Web of Science due to its broader disciplinary coverage, which encompasses most of the contributions indexed in Web of Science as well (Gusenbauer & Haddaway, 2020). The search was integrated with targeted consultations of Web of Science and Google Scholar to identify complementary contributions, highly cited studies, and foundational theoretical works frequently referenced in the Quality 4.0 literature.

Regarding the period, the search focused on studies published between 2015 and 2026, a time span that coincides with the phase of greatest development in the literature on Quality 4.0 and on the application of Industry 4.0 technologies to quality processes. Contributions published before this period were also included when considered theoretically foundational, as in the case of the literature on dynamic capabilities (Teece et al., 1997; Winter, 2003) and on Cost of Quality (Juran & Gryna, 1988).

The search strings were developed by combining keywords belonging to four fundamental conceptual areas, corresponding to the architecture of the proposed framework, as reported in Table 10. Searches were conducted in the title, abstract, and keyword fields, ensuring that the selected studies presented an explicit connection with the themes of the research.

Table 10. Search queries for the Scopus database.

Context:	<i>"Quality 4.0" OR "Industry 4.0" OR "Smart Manufacturing" OR "digital transformation" OR "Zero Defect Manufacturing" OR "Quality management 4.0" OR "manufacturing quality"</i>
AND	
Technologies:	<i>"Internet of Things" OR "IoT" OR "Machine Learning" OR "Artificial Intelligence" OR "Digital Twin" OR "Manufacturing Execution System" OR "MES" OR "Automation" OR "industrial automation"</i>
AND	
Operational capabilities:	<i>"Real-time monitoring" OR "predictive analytics" OR "operational capabilities" OR "process integration" OR "decision support" OR "quality management capabilities" OR "dynamic capabilities"</i>
AND	
Quality costs:	<i>"Cost of Quality" OR "Cost of Poor Quality" OR "quality costs" OR "scrap reduction" OR "rework reduction" OR "warranty costs" OR "quality performance" OR "failure costs"</i>

Note: Compiled by the author.

3.3.1 Inclusion and exclusion criteria

To ensure methodological transparency, reduce the risk of bias, and guarantee the replicability of the analysis, explicit inclusion and exclusion criteria were defined in accordance with the recommendations of the PRISMA 2020 protocol (Item 5, Page et al., 2021). The criteria were applied incrementally during the screening and eligibility assessment phases.

Inclusion criteria (IC)

IC-1. Peer-reviewed scientific articles, literature reviews, empirical studies, or theoretical contributions published in accredited journals or relevant conference proceedings in the field.

IC-2. Documents published between 2015 and 2025; exceptions are allowed for theoretically foundational contributions published before this period (for example, literature on dynamic capabilities, Cost of Quality, or organizational learning).

IC-3. Documents written in English or Italian.

IC-4. Documents addressing at least one of the following areas: Quality 4.0 or Industry 4.0 technologies in manufacturing contexts; digital quality management; Cost of Quality or Cost of Poor Quality; operational capabilities enabled by digital technologies; transformation of quality processes through digitalization.

IC-5. Documents provide evidence useful for understanding the causal mechanisms that connect digital technologies, operational capabilities, and the economic performance of quality in manufacturing systems.

Exclusion criteria (EC)

EC-1. Duplicate document, already identified through a previous search in the same or another database. (Applied during the identification phase, before screening.)

EC-2. Document not available in full text through the consulted bibliographic resources.

EC-3. Document lacking a connection with the manufacturing and industrial context, or relating to different sectors (for example, healthcare, services, public administration) without theoretically transferable elements.

EC-4. Document focused exclusively on the technical aspects of digital technologies, without implications for operational quality management or economic performance.

EC-5. Document lacking evidence useful for reconstructing the causal mechanisms between technologies, operational capabilities, and CoPQ reduction.

EC-6. Document of a predominantly commercial, divulgate nature or lacking documented peer review.

3.3.2 Study selection process

The study selection process was conducted in accordance with the recommendations of the PRISMA 2020 protocol and was articulated into four sequential phases: identification, screening, eligibility assessment, and inclusion. The overall process is illustrated in the PRISMA flow diagram shown in Figure 3.

Phase 1 – Identification

The application of the search strategy across the databases produced a total of 520 records. Of these, 486 records were identified through searches in the main databases (Scopus as the primary source, integrated with Web of Science), while 34 additional records were identified through complementary searches in Google Scholar and through manual consultation of the bibliographies of the most relevant

contributions. In accordance with the recommendations of the PRISMA 2020 protocol, dataset deduplication was performed before screening: 68 duplicate records, resulting from the parallel interrogation of the different sources, were removed, reducing the number of records to be screened to 452.

Phase 2 – Screening

The 452 records were screened through the systematic analysis of titles and abstracts. The assessment was conducted by systematically applying the inclusion and exclusion criteria defined in Section 3.3.1. In accordance with Page et al. (2021), for each excluded record the main reason for exclusion was recorded. At the end of this phase, 327 records were excluded for the following reasons:

- Lack of connection with the manufacturing or industrial context (EC-3);
- Exclusive focus on the technical aspects of technologies without implications for quality management (EC-4);
- Belonging to non-manufacturing sectors without theoretical elements transferable to the proposed framework (EC-3);
- Predominantly commercial, divulgate, or non-peer-reviewed content (EC-6);
- Lack of compliance with the time period (IC-2) or with the required thematic relevance (IC-4).

At the end of this phase, 125 records were considered potentially eligible and were retrieved for full-text assessment.

Phase 3 – Eligibility assessment

The full text of the 125 articles was examined in detail to verify their actual usefulness with respect to the objectives of the research. For each excluded document, the main reason for exclusion was recorded, in accordance with the recommendations of Item 16a of the PRISMA 2020 protocol (Page et al., 2021). In this phase, 41 articles were excluded for the following reasons:

- Lack of evidence useful for reconstructing the causal mechanisms between digital technologies, operational capabilities, and CoPQ reduction (EC-5);
- Contributions relating to non-manufacturing sectors without theoretical elements transferable to the research context (EC-3);
- Lack of connection with the CoPQ categories analyzed in the framework (EC-4, EC-5);
- Predominantly commercial content or lacking documented peer review (EC-6).

Phase 4 – Inclusion

At the end of the selection process, 84 studies were included in qualitative synthesis and used as the theoretical and empirical basis for the development of the mechanistic framework. The corpus includes foundational theoretical articles, systematic literature reviews, and empirical studies, covering the disciplines of Quality 4.0, Industry 4.0, Cost of Quality, dynamic capabilities, and digital manufacturing systems.

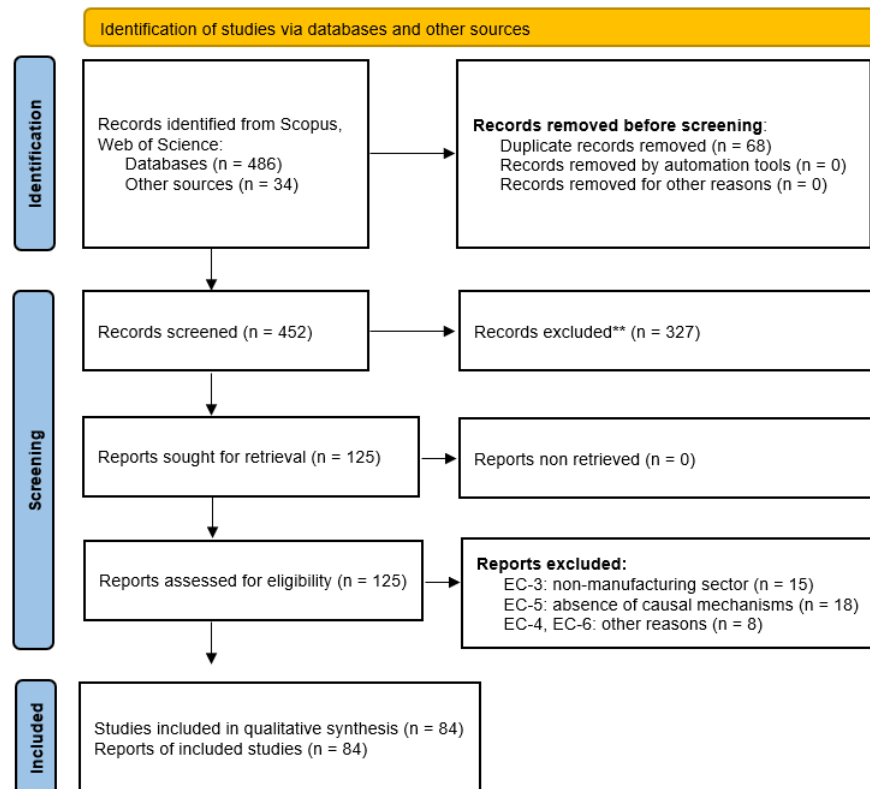


Figure 3. PRISMA 2020 flow diagram.

Source : Page MJ et al. BMJ 2021;372: n71. Adapted for the present research (Quality 4.0 and CoPQ).

3.4. Data extraction and structuring of evidence

To ensure methodological transparency and traceability in the literature review process, the 84 included studies were analyzed through a structured data extraction process articulated into four sequential phases, each corresponding to a distinct level of the architecture of the proposed mechanistic framework.

Each of the 84 included studies was individually coded using a structured extraction matrix comprising four dimensions: the Quality 4.0 technology addressed, the operational capability enabled, the quality

process transformed, and the CoPQ category affected. For each study, the technology dimension was coded based on the technology explicitly discussed by the authors; the operational capability dimension was coded based on the functional description of what the technology enabled the organization to do (e.g., detect, predict, respond); the transformed process dimension was coded based on the specific quality management activity affected; and the CoPQ category dimension was coded based on the cost implications explicitly or implicitly discussed by the authors, classified according to the PAF framework (Prevention, Appraisal, Internal Failure, External Failure). This structured coding procedure ensured that the relationships proposed in the mechanistic framework were grounded in a systematic reading of the literature, rather than in an unstructured or purely narrative synthesis.

Technology characterization

The first phase of the analysis concerned the identification and characterization of the Quality 4.0 technologies most recurrent in literature. For each technology, information was extracted regarding main functionalities, type of data generated or processed, role in quality processes, documented manufacturing applications, and operational mechanisms associated with performance improvement.

Through this process, five technologies considered particularly relevant to the research were selected: IoT, ML, Automation, Digital Twin, and MES. The selection was not determined by the mere diffusion of the technologies in literature, but by the presence of sufficient evidence to support the subsequent identification of clearly distinguishable and measurable operational capabilities.

Mapping of operational capabilities

The second phase concerned the identification of the operational capabilities enabled by the five selected technologies. Capabilities were defined as emerging operational capabilities that modify the way the organization observes, interprets, coordinates, and controls quality processes. This intermediate level of analysis represents one of the central elements of the entire methodology, since the framework assumes that technologies do not directly generate economic improvements, but that such effects are mediated by operational capabilities.

Documentation of CoPQ impact

The third phase concerned the documentation of evidence relating to the impact of operational capabilities on the different categories of CoPQ. The analyzed literature rarely describes explicitly the connection between digital technologies and CoPQ; it was therefore necessary to reconstruct such relationships through a process of theoretical inference supported by empirical evidence.

For each study, the reported effects on quality indicators and operational performance were identified: reduction of defects, decrease in rework, reduction of scrap, improvement in process conformity,

reduction of complaints, decrease in inspection activities, and increase in preventive effectiveness. These results were subsequently classified according to the traditional categories of CoPQ: Internal Failure Costs, External Failure Costs, Prevention and Appraisal Costs, and Hidden Quality Costs.

Tracking of economic outcomes

The final phase of evidence extraction was dedicated to the identification of the economic outcomes documented in the literature. The objective was not to build a meta-analysis of the economic benefits of Quality 4.0 technologies, but to verify the existence of empirical evidence consistent with the causal mechanisms identified in the research. For each contribution, indicators such as reduction in CoPQ, decrease in production costs, reduction in losses due to defects, productivity improvement, and reduction in maintenance and warranty costs were recorded.

3.5. Framework development and theoretical consistency assessment

The development of the proposed framework was carried out through an iterative process of theoretical synthesis, conceptual integration, and continuous comparison with the empirical evidence available in the literature. Unlike traditional empirical studies, in which validation occurs through the statistical analysis of collected data, the present work adopts a theory-building perspective, in which the robustness of the framework depends on the logical coherence of the proposed relationships and on their compatibility with existing evidence.

The framework was progressively developed starting from the results of the literature review. In the first phase, the Quality 4.0 technologies most recurrent in studies devoted to the digitalization of quality were identified. Subsequently, attention shifted to the operational capabilities enabled by each technology. The third level of analysis concerned the transformations of quality processes generated by the capabilities. Finally, the relationships between process transformations and CoPQ categories were reconstructed through the analysis of the empirical evidence documented in the included studies.

The theoretical consistency of the framework was assessed through three main criteria. The first criterion concerns internal coherence: all the causal relationships included in the framework are consistent with the theoretical definitions of the constructs used. The second criterion concerns theoretical triangulation: the proposed relationships do not derive from a single research stream but are supported by evidence from different disciplines. The third criterion concerns congruence with empirical evidence: the proposed causal relationships are compatible with the results of empirical studies documented in real industrial contexts.

3.6. Limitations and scope of application

Like any research based on the theoretical construction of a conceptual framework, the present study presents some limitations that must be considered when interpreting the results.

The first limitation concerns the absence of direct empirical validation. The framework was developed through the systematic integration of the evidence available in literature and not through the analysis of data collected in a specific industrial context. Future empirical research could help verify the validity of the identified relationships and quantify the intensity of the effects associated with the different operational capabilities.

The second limitation concerns the heterogeneous nature of the literature used. The framework integrates contributions from different disciplines and from industrial contexts that are not always homogeneous. Although such heterogeneity represents one of the strengths of the adopted approach, it also entails variability in the operational definitions of the constructs and in the metrics used to measure outcomes.

The third limitation concerns the selection of the technologies considered. The research focuses on five technologies considered particularly relevant for the digital management of quality: IoT, Machine Learning, Automation, Digital Twin, and MES. The framework does not exhaust the entire technological landscape of Industry 4.0; future research could integrate emerging technologies such as blockchain, augmented reality, edge computing, or advanced robotics.

Regarding the field of application, the framework was developed specifically for the manufacturing sector. The proposed causal relationships reflect processes typical of industrial production, such as process monitoring, quality control, nonconformity management, maintenance, and traceability. Extending the model to different contexts would require theoretical and methodological adaptations.

4. Mechanistic Framework: Causal Chains and Integration

Chapter 2 developed the theoretical and technological foundations necessary to understand Quality 4.0. Through the analysis of five key technologies, Internet of Things, Machine Learning, Automation, Digital Twin, and Manufacturing Execution Systems and their mapping against the dimensions of sensing, seizing, and reconfiguring in the Dynamic Capabilities framework (Teece et al., 1997; Teece, 2007), the five fundamental operational capabilities that structure the present work were identified: observability, predictability, rapid response, operational-design integration, and coordination. Section 2.3.3 also formalized the explanatory logic adopted, framing the technology-capability-process relationships within a mechanistic approach (Hedström & Ylikoski, 2010).

This chapter introduces the second level of proposed theoretical architecture. If Chapter 2 clarified why technologies do not produce value directly but through operational capabilities, Chapter 4 clarifies how such capabilities concretely act upon quality processes and through which mechanisms they may influence the categories of CoPQ. The gap identified in Section 2.3.1, the absence of explicit causal explanations between digitalization and economic outcomes, is addressed through the reconstruction of the causal chains that the proposed framework articulates between each technology and the specific components of CoPQ.

The chapter is structured into five sections. Section 4.1 analyzes the evidence of fragmentation in literature and the decision-support gap that motivates the development of the framework. Section 4.2 presents the five operational capabilities and the transformations they may produce in traditional quality management processes. Section 4.3 examines the four categories of CoPQ in the context of digitalization and the economic logic that justifies their linkage with operational capabilities. Section 4.4 synthesizes the causal pathways through Table 11 and Figure 4. Section 4.5 analyzes the potential synergistic effects and the contextual factors that condition their intensity.

4.1. Problem statement: Fragmentation in quality digitalization literature

4.1.1 Isolated studies on technologies: the technology-centric perspective

One of the main causes of the fragmentation identified in the literature on quality digitalization lies in the very structure of research devoted to Industry 4.0 technologies. Although in recent years a considerable number of studies have been produced on IoT, AI, Machine Learning, Digital Twin, Manufacturing Execution Systems, and other digital technologies, these contributions have mainly

developed as independent research streams, characterized by different objectives, methodologies, and evaluation criteria.

The available evidence suggests that most of the literature adopts a technology-centric perspective, in which technology constitutes the main unit of analysis. In this approach, attention is directed toward the technical characteristics of digital solutions, implementation methods, achieved performance, and opportunities for application in production processes. Although this perspective has contributed significantly to understanding the potential offered by digital transformation, it has also favored a progressive specialization of scientific knowledge.

Baran and Korkusuz Polat (2022), through a systematic literature review on the integration of Total Quality Management and Industry 4.0, highlight how the existing studies are organized around specific enabling technologies. The authors identify IoT, Big Data Analytics, AI, Cloud Computing, Cyber-Physical Systems, and Additive Manufacturing as the main research areas, showing how each of them has generated its own autonomous evolutionary path.

Sony et al. (2020), in their narrative literature review, observe that a large share of contributions focuses on identifying the digital technologies considered relevant for quality, the information infrastructures necessary for their implementation, and the competencies required by organizations. However, the authors emphasize that understanding the mechanisms through which such technologies generate organizational value remains one of the main open challenges in the field.

Salimbeni et al. (2023), analyzing 129 Argentine manufacturing firms, show that the organizations most advanced in quality management increasingly adopt technologies such as IoT, Cybersecurity, and Cloud Computing. The study provides important indications regarding the levels of diffusion of digital technologies but remains focused on the presence of the technologies and the degree of organizational readiness, without developing a detailed explanation of the relationships connecting such technologies to the specific categories of CoPQ.

As highlighted by Antony et al. (2022), the very definition of Quality 4.0 remains characterized by significant conceptual heterogeneity. Through an international survey conducted with industry experts, the authors show how some interpreters associate the concept with digital technologies, while others emphasize aspects related to organizational capabilities, quality culture, and data-driven decision processes. In light of these considerations, technological literature appears fundamental but insufficient: while it provides an important knowledge base on the characteristics and applications of Industry 4.0 technologies, it still does not offer an integrated model capable of systematically linking technologies to the transformation of quality processes and the consequent economic effects. This limitation represents the first element that justifies the adoption of a capability-centric perspective in the proposed framework.

4.1.2 Isolated studies on CoPQ reduction strategies

The fragmentation highlighted in technological literature finds a similar counterpart to studies devoted to reducing the Cost of Poor Quality. Although research on quality costs has reached a high level of theoretical and methodological maturity, a large share of the available contributions continues to analyze cost-reduction strategies as organizational initiatives that are independent of the digital technologies that could enable or strengthen them.

Historically, the literature on Cost of Quality has developed around the identification, classification, and measurement of the costs associated with quality. The models derived from the work of Feigenbaum (1956) and Juran (1951), later consolidated through the Prevention-Appraisal-Failure (PAF) framework, have provided organizations with useful tools for identifying the main sources of economic inefficiency associated with defects, rework, scrap, customer complaints, and inspection activities.

Empirical evidence indicates the economic relevance of such strategies. Schiffauerova and Thomson (2006), in their review of the literature on Cost of Quality models, show that numerous studies have demonstrated the possibility of significantly reducing total quality costs through increased investment in preventive activities. More recently, Indra et al. (2025), analyzing the application of the PAF model in a manufacturing context, show that strengthening preventive activities enabled an overall reduction in quality costs of 84.1%.

Despite the robustness of this evidence, most of the literature on CoPQ tends to focus on improvement strategies without systematically examining the technological mechanisms that could make them possible. If the technological literature tends to focus on the characteristics and performance of individual technologies, the literature on CoPQ focuses primarily on final economic effects. What is missing is an intermediate level of analysis capable of explaining how specific technologies contribute to the development of operational capabilities that, in turn, make it possible to reduce the different cost categories.

4.1.3 Missing causal mechanisms linking technologies to CoPQ reduction

The literature analysis shows that the fragmentation between studies on digital technologies and those devoted to the Cost of Poor Quality does not simply represent a problem of thematic separation. The main criticality lies in the absence of a structured explanation of the mechanisms through which quality digitalization translates into measurable economic benefits.

A large share of the available studies focuses on input-output relationships: on the one hand, investments in digital technologies are analyzed, and on the other, improvements in operational performance are reported. However, the pathway linking technology adoption to final economic outcomes is rarely made

explicit in a rigorous way. The existence of benefits is frequently demonstrated, while the mechanisms generating them remain insufficiently explained (Sony et al., 2020; Carvalho et al., 2021; Antony et al., 2022).

The literature on dynamic capabilities offers a particularly relevant contribution to understanding this issue. In this perspective, technologies represent resources that acquire value only when they are integrated into specific organizational and operational capabilities. Performance therefore does not derive directly from the availability of technology, but from the organization's ability to use such resources to modify its processes, improve decision-making, and adapt to operating conditions (Teece et al., 1997; Winter, 2003; Helfat & Peteraf, 2003). Applied to the context of Quality 4.0, this interpretation suggests that the reduction of CoPQ is not the direct result of adopting digital technologies, but rather of those technologies' ability to enable new ways of observing, predicting, coordinating, integrating, and responding operationally.

In light of these considerations, the main gap identified in the literature does not concern the absence of evidence regarding digital technologies or quality costs, but rather the lack of a causal model capable of systematically linking these two areas. The need to fill this theoretical void constitutes the conceptual foundation of the framework proposed in this research.

4.1.4 Decision-support gap for investment prioritization

The limitations highlighted in the previous sections do not represent an exclusively theoretical issue. The fragmentation of the technological literature, the separation between studies on digitalization and those on CoPQ, and the absence of explicit causal mechanisms have direct consequences for the decision-making process of manufacturing organizations.

Organizations frequently face multiple technological alternatives, monitoring systems based on IoT, predictive analytics platforms, advanced automation solutions, Digital Twins, and Manufacturing Execution Systems, each of which promises potentially significant benefits. Although firms have detailed information regarding the categories of CoPQ that most affect their performance, it is often more difficult to establish which technologies or digitalization initiatives are most capable of acting on those categories (Bharadwaj et al., 2013; Verhoef et al., 2021).

A further critical issue concerns the transferability of the available evidence. Many studies document success cases associated with the implementation of specific technologies, but these results are often influenced by the characteristics of the industrial context, the level of organizational maturity, and the implementation methods adopted. In the absence of a model that identifies the underlying mechanisms, it becomes difficult to understand whether the benefits observed are attributable to the technology itself or to the operational capabilities developed during the implementation process.

In light of these considerations, a significant decision-support gap emerges in the current literature.

Although there is substantial evidence regarding the benefits of digital technologies and the importance of reducing CoPQ, a conceptual tool is still lacking that can systematically connect these elements and support the prioritization of investments. The mechanistic framework proposed in this research arises precisely from the need to fill this gap.

4.2. Operational capabilities and the transformation of quality processes

Chapter 2 demonstrated how each of the five selected technologies enables a specific operational capability, derived from the dimensions of sensing, seizing, and reconfiguring in the Dynamic Capabilities framework (Teece et al., 1997; Teece, 2007). The selection of these five capabilities follows the theoretical derivation established in Section 2.3.3: the systematic literature review identified, for each technology, its predominant functional contribution, which was then mapped onto the sensing, seizing, and reconfiguring dimensions of Teece's Dynamic Capabilities framework. This mapping, rather than an inductive pattern extracted from the literature alone, provides the theoretical justification for the five capabilities and for the exclusion of alternative sets. This section analyzes the transformations that these capabilities produce in traditional quality management processes. The objective is not to redescribe the technologies which were already discussed in Chapter 2, but to identify the intermediate operational mechanisms that make the transition from technology adoption to process change possible. The economic implications of each transformation, in terms of the categories of CoPQ, are developed in Section 4.3.

4.2.1 Observability: Real-time defect detection (IoT)

As illustrated in Section 2.1.1, the IoT constitutes the primary enabler of the capability of observability, understood as the possibility of inferring the real state of the production process through the continuous analysis of the information generated by its physical and digital components (Atzori et al., 2010; Kusiak, 2018).

In traditional manufacturing systems, defect detection occurs through periodic inspections and sample checks. This logic introduces a structural information latency: between the appearance of a deviation and its identification, an interval elapses during which the process continues to produce under nonconforming conditions. IoT transforms this paradigm by replacing episodic detection with continuous monitoring and making the production process observable throughout all its operational phases (Salimbeni et al., 2023).

The transformation concerns not only the frequency of measurements, but the very nature of the available information. As Psarommatis et al. (2022) emphasize in the context of Zero-Defect

Manufacturing, the systematic prevention of defects requires the ability to identify early signals of process degradation at an early stage. Defects rarely appear suddenly; in most cases, they are preceded by small operational deviations that, if properly observed, can be intercepted before they produce significant consequences. In the proposed framework, this mechanism is interpreted as a reduction in information latency: the time window between the onset of the deviation and its identification is expected to contract proportionally to the coverage and frequency of the sensors. The implications of this transformation for the categories of CoPQ are developed in Section 4.3.

4.2.2 Predictability: Anticipatory prevention (Machine Learning)

ML enables the capability of predictability, defined as the organizational ability to identify early operating conditions associated with a higher probability of generating future nonconformities (Wuest et al., 2016). In traditional quality management systems, prevention is based on historical experience, periodic data analysis, and retrospective root-cause identification. Although these approaches can reduce recurring defects, they remain limited by their reliance on events that have already occurred. Predictability transforms this logic by allowing the organization to infer, from current process conditions, the probability that a defect will occur before the nonconformity materializes. In this way, prevention becomes anticipatory rather than merely corrective.

In traditional systems, prevention is based on standardized procedures, predefined time intervals, and the analysis of events that have already occurred. Preventive resources are distributed uniformly, regardless of the actual level of risk associated with each stage of the process. Predictability transforms this logic by replacing generalized prevention with risk-guided selective prevention: resources are concentrated at the moments and in the areas where the probability of defects is effectively high (Ayvaz & Alpay, 2021; Liu et al., 2022).

The transformation does not simply consist in introducing a new analytical tool, but in changing the underlying logic of operational risk management. A predictive system does not replicate the human activity of inspection; it replaces it with a continuous process of risk assessment based on historical patterns and current operational signals. In the proposed framework, this mechanism is interpreted as a reduction in the cost of uncertainty: the organization no longer over-invests in generalized prevention to compensate for the lack of predictive information but can instead concentrate on resources where risk is high. The link with the categories of CoPQ is developed in Section 4.3.

4.2.3 Rapid Response: Quick failure mitigation (Automation)

Automation technologies enable the capability for rapid response, defined as the organizational capability to activate corrective actions in sufficiently short times to prevent a deviation from propagating through the production system before it is contained (Hermann et al., 2016).

In traditional systems, the response to a non-conformity requires a sequence of activities, identification, communication, analysis, decision, implementation, in which each phase introduces a delay. Automation compresses this sequence through closed-loop systems, in which detection and intervention are integrated within a continuous operating cycle. The transformation that derives from this concerns not only speed, but the very nature of the corrective process: from sequential manual reaction to automatic process adaptation (Lee et al., 2015; Tao et al., 2018).

This capability is particularly relevant in contexts where the speed of the production process is high: the economic advantage of rapid response is expected to grow proportionally with the production volume that would be involved in the absence of containment. In the proposed framework, this mechanism is interpreted as containment of economic impact: the defect cannot be eliminated *ex ante*, but its propagation is limited *ex post* through the speed of the corrective intervention. The implications for the CoPQ categories are analyzed in Section 4.3.

4.2.4 Operational-Design Integration: Virtual simulation (Digital Twin)

The Digital Twin constitutes the primary enabler of the capability for operational-design integration, defined as the possibility of systematically connecting design, simulation, and optimization activities with real productive operations through a dynamically updated virtual environment (Grieves & Vickers, 2017; Tao et al., 2019).

In traditional systems, organizational learning occurs through physical experimentation: modifications to process parameters, new operational configurations, and design variations are validated through real tests that consume materials, machine time, and productive capacity. Digital Twin transforms this logic by transferring a significant share of experimentation to the virtual environment. The organization can analyze alternative scenarios, test operational modifications, and evaluate the effects of design decisions before their physical implementation (Jones et al., 2020; Kritzinger et al., 2018).

The most relevant transformation therefore does not concern simulation, but the capacity to shift the moment of validation: from physical implementation, when the cost of correction is already high, to the virtual design phase, when the cost is still low. In the proposed framework, this mechanism is interpreted as a reduction of the cost of organizational learning: the organization can acquire knowledge about the behavior of its own productive system without bearing the cost of real errors. The implications for the CoPQ categories are developed in Section 4.3.

4.2.5 Coordination: Function integration (MES)

Manufacturing Execution Systems enable the capability for coordination, defined as the organizational capacity to integrate information flows, operational activities, and decisional processes distributed across different functions, hierarchical levels, and technological systems (Kletti, 2007; Shojaeinasab et

al., 2022).

In traditional manufacturing systems, information relating to defects, scraps, reworks, and operational performance is managed separately by production, quality, maintenance, and planning. This fragmentation generates organizational inefficiencies in which understanding the cause of a non-conformity requires complex reconstruction and coordination activities across different functions. The MES transforms this logic by creating a shared information infrastructure in which data are integrated, contextualized, and accessible in real time to all functions involved in the decisional process (Fischer et al., 2021; Saenz de Ugarte et al., 2009).

The transformation that derives from this is not technological but organizational: the functions that previously operated with partial visibility and delayed information begin to share a common operational framework. In the proposed framework, this mechanism is interpreted as elimination of organizational quality failures: non-conformities that originate not from a technical deviation of the process, but from discontinuities in the circulation of information, communication delays, data fragmentation, asymmetric visibility, can be reduced through the shared infrastructure. The connection with the CoPQ categories is developed in Section 4.3.

4.3. The Cost of Poor Quality categories in the Quality

4.0 context

The quality process transformations analyzed in Section 4.2 find their economic translation in the categories of the CoPQ. The present section examines each category of the PAF model, internal failure costs, external failure costs, prevention costs, appraisal costs, and hidden costs, identifying the economic logic through which the operational capabilities can influence their level. For each category, the analysis starts with the economic structure of the category itself and, through explicit references to the capacities developed in Section 4.2, describes the reduction mechanisms.

4.3.1 Internal failure costs: defects, rework, and scrap

Internal failure costs encompass all losses generated by non-conformities identified before the product reaches the end customer: scraps, reworks, repairs, production stoppages, and inefficient material consumption (Schiffauerova & Thomson, 2006; Campanella, 1999). Their magnitude depends on three fundamental variables: the frequency with which deviations arise, the speed with which they are identified, and the speed with which they are contained or corrected.

The first two variables are directly influenced by the capability of observability (Section 4.2.1): continuous monitoring affects informational latency, limiting the quantity of production that continues in non-conforming conditions before process normalization. Smart Manufacturing studies show how

continuous monitoring allows operational anomalies to be identified in a significantly faster way compared to traditional inspection systems, with a corresponding reduction in cumulative scraps (Chen et al., 2018; Mourtzis et al., 2018). Predictability (Section 4.2.2) intervenes on the frequency of deviations themselves: by identifying high-risk operating conditions before the defect appears, it is possible to activate targeted preventive interventions that reduce the probability of occurrence (Wuest et al., 2016; Ayvaz & Alpay, 2021).

The third variable, containment speed, is influenced by rapid response (Section 4.2.3): closed-loop systems that integrate detection and corrective action limit the number of units involved in an already initiated deviation (Psarommatis et al., 2022; Cheng, 2022). Operational-design integration (Section 4.2.4) affects a structural source of defects: configuration and design errors that, in traditional systems, emerge only during real production, can be anticipated in the virtual environment (Tao et al., 2019). Coordination (Section 4.2.5) further contributes by reducing the share of non-conformities that originate from organizational discontinuities rather than from technical deviations (Fischer et al., 2021; Shojaeinasab et al., 2022).

The framework interprets the reduction of internal failure costs as the aggregate effect of these five mechanisms. It is important to clarify that this reduction is not automatic: for it to materialize, the operational capabilities must translate into effective changes in decisional processes and quality management practices. The mere availability of sensors, data, or algorithms does not guarantee an improvement in economic performance in the absence of adequate organizational structures for their use.

4.3.2 External failure costs: customer returns and warranty claims

External failure costs emerge when the defect bypasses internal control mechanisms and reaches the end customer. This category encompasses costs associated with returns, claims, warranty replacements, technical assistance interventions, product recalls, and management of field non-conformities (Campanella, 1999; Schiffauerova & Thomson, 2006). Their magnitude depends on two distinct factors: the probability that a defective product escapes internal control and reaches the market, and the organization's capacity to contain the consequences once the problem has been identified.

The first factor is influenced by the set of operational capabilities that reduce the frequency and propagation of defects throughout the process: observability, predictability, and rapid response (Sections 4.2.1–4.2.3) contribute indirectly to reducing the number of defective products that reach the final phases of the production process. The so-called escaped defects, non-conformities that bypass internal control systems, progressively decrease as the coverage and effectiveness of detection and containment capacities increase (Chen et al., 2018; Song et al., 2018).

The second factor, the capacity to limit consequences once the problem emerges on the market, is

influenced primarily by the capability for coordination (Section 4.2.5). The traceability and visibility of the entire production chain enabled by MES allow the genealogy of the product to be rapidly reconstructed, identifying with precision the lots effectively involved (Shojaeinasab et al., 2022; Fischer et al., 2021). When non-conformity emerges on the market, this can contribute to reducing the extent of corrective action, limiting recall and replacement costs. The framework interprets this mechanism as a reduction of the cost of informational uncertainty in post-sales phases.

Compared to internal failure costs, the effects on external failure costs tend to manifest over longer timeframes and are influenced by factors that the organization does not entirely control: customer behavior, regulatory context, reputational dynamics. The proposed framework does not claim that digitalization eliminates such costs but suggests that the systematic reduction of internal non-conformities and the improvement of traceability create the necessary conditions to limit their frequency and magnitude.

4.3.3 Prevention and appraisal costs: investments and monitoring

Unlike internal and external failure costs, which represent the economic consequences of poor quality, prevention costs and appraisal costs correspond to the resources that the organization invests to prevent the occurrence of non-conformities or to verify their absence. The PAF model encompasses activities such as training, quality planning, preventive maintenance, monitoring, inspection, testing, and auditing (Campanella, 1999; Schiffauerova & Thomson, 2006).

In the Quality 4.0 context, the relationship between digitalization and these cost categories is more complex compared to failure costs. Digital technologies do not necessarily determine an immediate reduction of prevention and appraisal costs; in many cases they initially increase them, since they require investments in infrastructures, sensors, analytical platforms, and specialized competencies. The framework interprets this phenomenon not as a paradox, but as a reallocation of resources: a growing share of investment is shifted from reactive correction activities toward digital prevention and monitoring activities (Mittal et al., 2019; Wan et al., 2016).

The economically relevant question therefore does not concern the absolute increase or decrease of these costs, but their relationship with the other CoPQ categories. The PAF literature suggests that an increase in prevention investments is justified when it produces a proportionally greater reduction in failure costs (Schiffauerova & Thomson, 2006). The capability for predictability (Section 4.2.2) is particularly relevant in this perspective: its value does not consist in reducing preventive expenditure, but in increasing the ratio between invested resources and non-conformities effectively avoided, improving the economic efficiency of prevention. Similarly, observability (Section 4.2.1) can progressively replace manual inspection activities with automatic monitoring systems, modifying the structure of inspection costs without necessarily reducing them in absolute value.

The proposed framework interprets prevention and appraisal costs not as simple cost items to minimize, but as strategic investments that enable the development of the operational capabilities necessary to reduce failure costs. The optimal balance between these categories depends on the organization's specific CoPQ profile, a topic addressed in Section 4.5.

4.3.4 Hidden quality costs: missed opportunities and reputational damage

Numerous authors have highlighted how a significant portion of the economic consequences of poor quality remains excluded from traditional measurement systems. Hidden quality costs encompass loss of commercial opportunities, deterioration of corporate reputation, reduction of customer trust, organizational inefficiencies, and diminishment of the capacity to adapt to market changes (Campanella, 1999; Schiffauerova & Thomson, 2006). Unlike the other categories of the PAF model, these costs are difficult to quantify through conventional accounting systems but can significantly influence competitive performance over the long term.

The connection between Quality 4.0 operational capabilities and hidden costs develops through causal paths that are less direct compared to those observed in the other categories. The systematic reduction of non-conformities achieved through observability, predictability, and rapid response contributes indirectly to strengthening the perceived reliability of the organization, reducing the risk of events that could undermine market trust (Garvin, 1987). The framework interprets this effect with caution: it is a relationship mediated by numerous contextual factors, difficult to isolate and measure empirically.

The capability for coordination (Section 4.2.5) assumes a particular role in the reduction of hidden costs of an organizational nature. Organizations characterized by high levels of informational integration tend to resolve problems more rapidly, to share knowledge more effectively, and to develop a greater capacity for organizational learning (Sony et al., 2020). Such characteristics do not necessarily produce benefits immediately visible in accounting systems, but the framework suggests that they can contribute to reducing hidden costs associated with decisional delays, duplication of activities, and loss of operational knowledge.

The capabilities for predictability and operational-design integration (Sections 4.2.2 and 4.2.4) can contribute to increasing the company's capacity to make data-driven decisions and to evaluate alternative scenarios before their implementation. The framework interprets this as a potential increase in the value of seized opportunities relative to missed ones. The connection between these capabilities and hidden costs remains nevertheless the most speculative of the entire causal chain proposed: the framework includes it as theoretical orientation, recognizing that its empirical verification requires measurement instruments and research designs more complex than those applicable to the other categories.

4.4. Causal synthesis: mechanistic pathways of the framework

The preceding sections have separately analyzed the transformations that each operational capability can produce in quality processes (Section 4.2) and the economic logic that justifies the connection between such transformations and the CoPQ categories (Section 4.3). The present section integrates these elements through a unified causal representation, in which each technology–capability–process–CoPQ pathway is synthesized in terms of its essential economic mechanism, reconstructed through theoretical inference from the reviewed literature rather than direct empirical measurement. Table 11 offers a comparative synthesis of the five pathways, while Figure 4 illustrates the integrated structure.

Table 11. Mechanistic framework: synthesis of Quality 4.0 → CoPQ causal pathways.

<i>Technology (Quality 4.0)</i>	<i>Operational Capability</i>	<i>Transformed Process</i>	<i>Process/Causal Mechanism</i>	<i>Influenced CoPQ Category</i>
<i>IoT (smart sensors)</i>	Observability	Defect detection: manual → real-time continuous	Reduction of informational latency: the window between deviation occurrence and identification is narrowed	Internal Failure Costs ↓ (Atzori et al., 2010 ; Kusiak, 2018)
<i>Machine Learning (predictive analytics)</i>	Predictability	Reactive prevention → anticipatory	Reduction of the cost of uncertainty: preventive resources are concentrated in the areas of highest actual risk	Prevention Costs (optimized); Internal Failure Costs ↓ (Wuest et al., 2016; Ayvaz & Alpaz, 2021)
<i>Automation (adaptive systems)</i>	Rapid Response	Corrective action: slow/manual → automatic closed loop	Containment of economic impact: defect propagation is limited ex post through the speed of intervention	Internal + External Failure Costs ↓ (Psarommatis et al., 2022 ; Cheng, 2022)

<i>Digital Twin (virtual simulation)</i>	Operational- Design Integration	Decision validation: physical → virtual	Reduction of the cost of organizational learning: experimentation is transferred from the physical to the digital system	Internal Failure Costs ↓ ; Appraisal Costs ↓ (Tao et al., 2019 ; Jones et al., 2020)
<i>MES (data integration)</i>	Coordination	Information alignment: siloes → shared infrastructure	Elimination of organizational quality failures: communicative discontinuities are removed through the shared infrastructure	Mainly supports Internal and External Failure Cost reduction, and indirectly affects other CoPQ categories through improved coordination and traceability

Note: Compiled by the author based on the literature review.

The first causal pathway (IoT → Observability) operates through the reduction of informational latency. In the proposed framework, this mechanism is interpreted as the contraction of the temporal window during which an out-of-control process continues to generate non-conformities without the organization being aware of it. The economic value of the mechanism is proportional to the volume of production involved in the interval between deviation occurrence and identification: the faster the identification, the lower the cumulative cost (Salimbeni et al., 2023; Schiffauerova & Thomson, 2006). The pathway primarily influences Internal Failure Costs, with secondary effects on traceability that also contribute to the reduction of External Failure Costs.

The second causal pathway (Machine Learning → Predictability) operates through the reduction of the cost of uncertainty. In the proposed framework, the mechanism suggests that the organization, instead of over-investing in generalized prevention to compensate for the lack of predictive information, can concentrate resources where the risk is effectively high. The expected result is not an absolute reduction of prevention costs, but an improvement of their economic efficiency: a lower redundancy in preventive expenditure, accompanied by a reduction in the frequency of events that generate failure costs (Wuest et al., 2016; Ayvaz & Alpay, 2021).

The third causal pathway (Automation → Rapid Response) operates through the containment of economic impact. Unlike the two preceding pathways, which influence the probability of deviation

occurrence, this pathway acts on the magnitude of the economic consequences of an event that has already occurred. In the proposed framework, closed-loop systems that integrate detection and corrective action can limit the propagation of the deviation along the production chain, reducing the volume of production involved before process normalization (Psarommatis et al., 2022; Cheng, 2022). The pathway primarily influences Internal Failure Costs, with indirect effects on External Failure Costs through the reduction of the number of potentially defective products.

The fourth causal pathway (Digital Twin → Operational-Design Integration) operates through the reduction of the cost of organizational learning. In the proposed framework, virtual simulation can allow experimentation and validation to be progressively shifted from the physical to the digital system. Design and configuration decisions that in traditional systems require costly physical tests can be evaluated in the virtual environment, anticipating the identification of potential sources of non-conformity (Tao et al., 2019; Jones et al., 2020). The pathway influences Internal Failure Costs by reducing configuration errors and contributes to External Failure Costs through the prevention of systemic defects of design origin.

The fifth causal pathway (MES → Coordination) operates through the reduction of organizational quality failures. In the proposed framework, the shared information infrastructure enabled by MES can eliminate organizational discontinuities, delays in communication, fragmentation of information, visibility asymmetries, which amplify the economic consequences of every non-conformity (Shojaeinasab et al., 2022; Fischer et al., 2021). Unlike the other pathways, which act on specific failure cost categories, coordination has a transversal effect on all CoPQ categories, since informational fragmentation is a systemic vulnerability that permeates the entire quality management process.

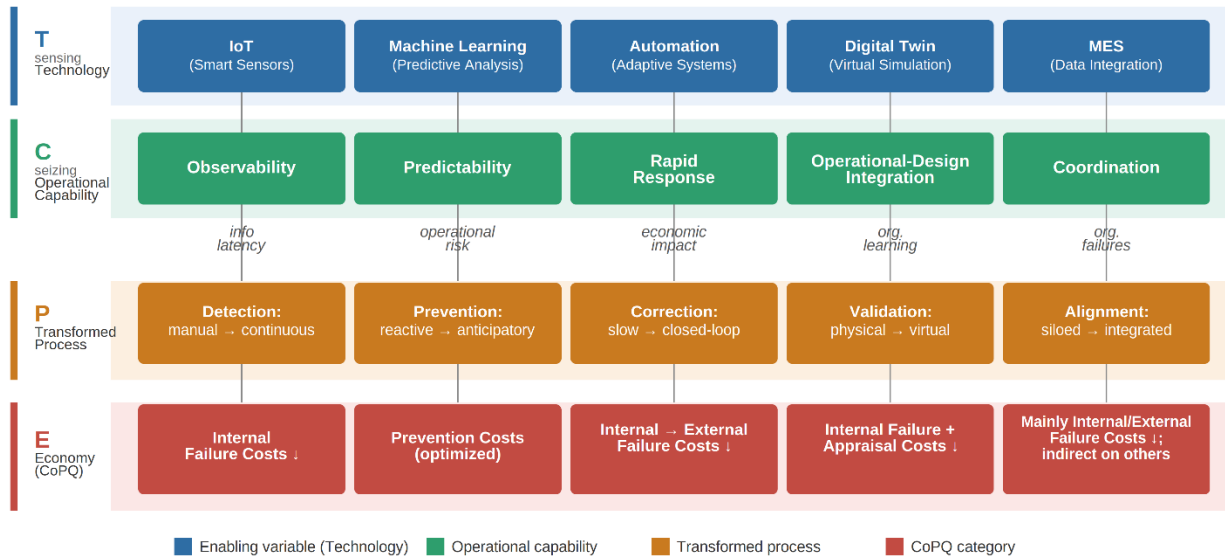


Figure 4. Mechanistic framework: Quality 4.0 → Operational capabilities → CoPQ.

Note: Compiled by the author.

As illustrated in Figure 4, the five causal pathways are not sequential but parallel and partially overlapping. Each operational capability contributes in a distinct way to the reduction of CoPQ through a specific economic mechanism. The analysis of the synergistic effects that emerge from the simultaneous integration of multiple capabilities is developed in Section 4.5.

4.5. Synergistic effects and contextual factors

4.5.1 Interaction between operational capabilities and potential amplification mechanisms

The five operational capabilities identified in the framework do not necessarily operate as independent elements. The Industry 4.0 literature suggests that the benefits of digital technologies tend to emerge more intensely from the integration of multiple instruments rather than from the isolated implementation of each one (Frank et al., 2019; Tortorella et al., 2021). This interdependence constitutes a potentially relevant mechanism: if the operational capabilities mutually reinforce each other through shared informational and decisional flows, the individual benefits of each could be amplified by their integration.

The interdependence relationships follow a logic consistent with the framework. The capability for observability (Section 4.2.1) provides the informational basis necessary for the development of reliable predictive models: the quality of data collected from IoT sensors directly conditions the accuracy of ML algorithms (Wuest et al., 2016; Salimbeni et al., 2023). In turn, predictability can enhance rapid response

by providing anticipatory signals that allow corrective actions to be activated before the deviation becomes visible in process parameters. The Digital Twin can benefit from the data generated by observability to continuously update the virtual model, making it progressively more faithful to the real behavior of the system (Jones et al., 2020; Tao et al., 2019). Coordination performs a transversal function: it distributes the information generated by the other capabilities across organizational functions, extending the number of actors who can use them for operational decisions.

From the integration of these relationships, the framework proposes that an amplification mechanism may emerge. The organization that simultaneously disposes of observability, predictability, and rapid response would not necessarily obtain merely the sum of individual benefits: the availability of continuous information, translated from predictive models into automatic actions, could create an operational learning cycle in which every event, including non-conformities, generates usable knowledge to improve future management. Such a cycle is not observable in the presence of a single capability but could emerge from the interaction among them. The framework interprets this as a potential emergent effect, consistent with the perspective of socio-technical systems (Pasmore et al., 2019) and with the logic of dynamic capabilities (Teece, 2007), without however affirming that it produces itself automatically or uniformly in all contexts.

One of the potential effects of integration concerns the progressive transformation of data into shared organizational knowledge. When observability, predictability, rapid response, virtual simulation, and coordination operate simultaneously, the framework suggests that a higher-level organizational capability may develop: the possibility of understanding the production system in real time, anticipating its future behaviors, and intervening in a coordinated manner. The reduction of the CoPQ would become in this context not only the result of individual corrective interventions, but an integrated effect of the digitalized quality management system. This interpretation, consistent with the literature on organizational capabilities (Sony et al., 2022), nonetheless remains subject to empirical and contextual verification.

4.5.2 Contextual factors and synergy configurations

The relationship between the adoption of Quality 4.0 technologies and the reduction of the CoPQ is neither linear nor universally uniform. The available literature highlights that organizations characterized by similar technological investments can obtain significantly different results in terms of economic quality performance (Frank et al., 2019; Salimbeni et al., 2023). This variability does not represent an anomaly but reflects the contextual nature of the benefits associated with digital transformation.

Three categories of factors can condition the intensity of the benefits. In the first place, the digital maturity of the organization: available technologies can prove little effective in the absence of analytical competencies, data governance, and data-driven decisional processes (Sony et al., 2022). In the second

place, the structure of the production process: high-speed and high-volume systems could benefit more from observability and rapid response capabilities, while processes with high design complexity could draw advantage primarily from operational-design integration. In the third place, the CoPQ profile: organizations with high Internal Failure Costs could prioritize different investments compared to those with External Failure Costs or hidden cost problems (Campanella, 1999; Schiffauerova & Thomson, 2006).

Synergistic configurations may not manifest uniformly but tend to take shape differently according to the operational characteristics of the company. In highly automated manufacturing contexts, the observability–rapid response chain could produce the most immediate benefits on the reduction of scrap and rework. In contexts of high product customization, the operational-design integration–coordination pathway could prove most relevant for preventing defects of design origin. In organizations with highly fragmented processes, the coordination enabled by MES could represent the capability with the greatest potential for reducing hidden costs and organizational failures.

The proposed framework therefore does not assume the existence of a universal optimal configuration but rather interprets the relationship between digitalization and CoPQ reduction as a context-conditioned phenomenon. This interpretation is consistent with the perspective of dynamic capabilities, according to which the value of organizational resources depends on the company's capacity to adapt them to specific environmental and competitive conditions (Helfat et al., 2007). A relevant managerial implication derives from this: investment decisions in Quality 4.0 cannot be based exclusively on the characteristics of available technologies, but should consider the organization's CoPQ profile, the level of digital maturity, and the specific operational priorities of the productive context.

5. Literature-Based Evidence on the Relationship between Quality 4.0 and CoPQ

The growing diffusion of Industry 4.0 technologies has generated a significant number of studies dedicated to the analysis of their effects on the operational and qualitative performance of manufacturing systems. Despite this growing attention, literature continues to present significant fragmentation: many studies focus on individual technologies and specific operational indicators, without establishing explicit connections with the economic categories of CoPQ. The framework developed in the preceding chapters was built precisely to address this gap, proposing a causal structure that connects technologies, operational capabilities, and quality cost categories (Sony et al., 2020; Salimbeni et al., 2023; Antony et al., 2022).

The present chapter analyzes the empirical evidence available in the literature regarding the impact of Quality 4.0 technologies on the different CoPQ categories. Rather than examining technologies in isolation, the analysis is organized according to the main categories of the PAF model, internal failure costs, external failure costs, prevention and appraisal costs, and hidden quality costs, allowing an economic perspective consistent with the logic of the proposed framework to be maintained (Farooq et al., 2017; Campanella, 1999; Schiffauerova & Thomson, 2006). The objective does not consist in demonstrating definitive causal relationships, since the available literature presents considerable methodological limitations that will be discussed in the concluding section. The objective is to evaluate the empirical plausibility of the relationships proposed in the framework and identify recurring patterns in the available evidence.

Throughout this analysis, three types of evidence are distinguished: direct evidence, where a study explicitly measures a reduction in a specific CoPQ category following the adoption of a Quality 4.0 technology; indirect evidence, where a study reports an improvement in a related operational indicator (e.g., defect rate, response time) from which an effect on CoPQ can reasonably be inferred; and theoretical inference, where the relationship is not empirically observed in the reviewed studies but is derived from the logical structure of the proposed framework. This distinction is applied consistently across the following sections, since not all the studies included in the review measure cost reductions directly.

5.1. Quality 4.0 and Internal Failure Costs

Internal failure costs represent one of the CoPQ categories most directly connected to Quality 4.0 applications. Such costs encompass all costs generated by defects identified before delivery to the customer: scraps, reworks, re-inspections, unplanned production stoppages, and productivity losses (Campanella, 1999; Farooq et al., 2017). The economic relevance of this category is documented by

numerous studies: Bris et al. (2022) show that internal failure costs often represent the most relevant component of total CoPQ in manufacturing contexts, while Sower et al. (2007a) and Schiffauerova & Thomson (2006) highlight how many organizations do not dispose of adequate systems to measure their actual magnitude.

ZDM literature provides particularly strong support for the relationship between Quality 4.0 technologies and reduction of internal failure costs. Psarommatis et al. (2022) show how predictive and preventive technologies allow the occurrence of defects to be significantly reduced, shifting the production system from a reactive to a preventive logic. The same research group, in a systematic review from 2024, documents how ZDM implementations that integrate IoT, Machine Learning, and automation systems produce documented reductions in defect rates, with direct effects on internal failure costs. Mayr et al. (2018a, 2018b) demonstrate empirically how automated defect detection through ML and edge computing allows intervention before the defect propagates along the production process, limiting reworks and the relative capacity losses.

A particularly relevant empirical example is provided by Alkhatib et al. (2025), who implement the Quality 4.0 PMQ framework in an automotive production context. The developed system integrates IoT sensors, ML algorithms, and real-time monitoring systems to predict process defects before their manifestation. The reported results show F1-score values above 0.98 and AUC close to 0.99, with significant reductions in defect rates and inspection times. The importance of this study does not reside solely in the accuracy metrics, but in the way the case concretely demonstrates the operational capability of Predictability and Observability, the abilities of ML and IoT respectively to intercept defects before they translate into scraps and reworks (Wuest et al., 2016; Ayvaz & Alpay, 2021; Carvalho et al., 2019).

Farooq et al. (2017) also provide an important contribution to the understanding of the link between quality, defects, and internal costs. Their study develops a Cost of Quality model to evaluate the trade-off between inspection costs and failure costs in real manufacturing systems, documenting defect reductions above 65% and productivity increases of 10% through optimization of inspection strategies. Mufato Reis et al. (2024) further reinforce this point through a case study in electronics manufacturing, showing how Industry 4.0 technologies allow inspection strategies to be optimized by jointly reducing appraisal costs and failure costs. Indra et al. (2025), in an empirical study conducted on a longitudinal basis, document a reduction of 84.1% of total CoPQ through a prevention-oriented approach, with improvement of process quality from 96.11% to 99.75%.

5.2. Quality 4.0 and External Failure Costs

External failure costs represent the economically most critical component of the CoPQ, since they encompass all costs associated with defects detected after delivery to the customer: claims, returns, warranties, product recalls, reputation loss, and reduction of the customer base (Campanella, 1999; Farooq et al., 2017). Unlike internal failure costs, the economic consequences of external failures do

not exhaust themselves in the direct cost of corrective intervention but propagate over time through the erosion of customer trust and the deterioration of the competitive position of the company (Bris et al., 2022; Faciane et al., 2024).

One of the most significant pieces of evidence in this direction comes from the study of Alkhatib et al. (2025), who implement the PMQ framework in an automotive production context. The ML and IoT-based monitoring system allows potential defects to be identified before they reach the end customer, reducing the probability of post-delivery non-conformities. The PMQ framework is configured as an early warning system that acts on Predictability capability, allowing defects to be intercepted that, in the absence of digital technologies, would have been detected only after delivery. This shift, from post-delivery detection to pre-delivery prevention, constitutes the primary mechanism through which Quality 4.0 technologies contribute to the reduction of external failure costs.

Fukuzawa et al. (2022), analyzing four Japanese manufacturing companies that invested in IoT systems, document improvements in customer satisfaction and reductions in post-sales returns, although direct economic quantification remains partial. Thomas (2024) highlights that one of the main sources of economic value of the Digital Twin consists in the reduction of warranty costs and product recall expenses, through the capacity to virtually simulate the behavior of the product before physical production. Psarommatis et al. (2024) show that many of the ZDM applications analyzed in their systematic review contribute specifically to the reduction of non-conformities detected by the customer, limiting the economic consequences of external failures.

Despite these results, literature still presents a significant limitation for this cost category. Many studies measure the impact of Quality 4.0 technologies through operational indicators, reduction of defect rates, improvement of predictive accuracy, increase in conformity levels, without directly connecting such improvements to the reduction of warranty costs, claims, or customer loss. The relationships proposed in the framework therefore prove plausible and supported by indirect evidence but require direct empirical validation through longitudinal studies that jointly measure operational and financial indicators (Mufato Reis et al., 2024; Schiffauerova & Thomson, 2006; Sower, 2007).

5.3. Quality 4.0 and Prevention and Appraisal Costs

Prevention and appraisal costs represent the Cost of Quality components associated with activities aimed at avoiding the generation of defects (prevention) and at verifying the conformity of products and processes (appraisal). Unlike failure categories, for which the objective consists of reducing losses, prevention and appraisal costs can both increase and decrease because of the adoption of Quality 4.0 technologies. The relationship between these categories is non-linear and depends on the logic with which technologies transform control activities (Farooq et al., 2017; Schiffauerova & Thomson, 2006; Sower et al., 2007b).

A confirmation of the transformation of appraisal costs emerges from the study of Farooq et al. (2017), who develop a Cost of Quality model to optimize inspection strategies. The results show how improvement of control activity accuracy, achievable through automated detection systems, allows the number of inspections necessary for a given conformity level to be reduced, lowering complex appraisal costs. Mufato Reis et al. (2024), in an automotive electronics case study, shows that the revision of inspection strategies supported by Industry 4.0 technologies can lead to significant reductions in control costs, allowing inspection resources to be concentrated in the most critical phases of the production process.

Galetto et al. (2020) further contribute to this stream of research by proposing a method to evaluate the robustness of defect and cost predictions in quality inspection planning for low-volume productions, addressing how the uncertainty inherent in these predictive models can affect the choice of the most effective and economically viable inspection strategy. This contribution is relevant for the present framework, since it highlights that the economic benefits of predictive and data-driven inspection approaches depend not only on model accuracy, but also on a correct assessment of the uncertainty surrounding their estimates.

Verna et al. (2022) extend this line of work by developing a cost breakdown model that integrates production costs with the main cost drivers involved in quality-related activities, including inspection, pre- and after-sales reworks, and unnecessary repairs due to nonconformities. Unlike earlier cost models that consider only production-related cost components, this approach explicitly separates the economic contribution of each quality-related activity, offering designers a practical tool for the economic evaluation of alternative inspection strategies during the early design phases, particularly in low-volume production contexts. This granular decomposition of quality-related costs is consistent with the logic of the proposed framework, which likewise seeks to disaggregate the Cost of Poor Quality into distinct categories to trace their specific economic mechanisms back to the operational capabilities that generate them.

The impact of digital technologies on the transformation of appraisal activities emerges with clarity in studies dedicated to automated inspection systems. Kamble et al. (2023) analyze digital quality management and intelligent inspection systems in smart manufacturing environments, highlighting how the automation of control activities allows the unit cost of inspection to be reduced and quality control coverage to be increased without proportional cost increases. Song et al. (2018) demonstrate how convolutional neural networks allow high-speed automated inspection with high accuracy levels, reducing dependence on costly manual inspections. Wu et al. (2023) and Ji & Nor (2023) show how Digital Twin systems integrated with deep learning techniques allow automated inspections with accuracy levels superior to traditional systems, reducing re-inspection costs.

In the Digital Twin domain, Thomas (2024) highlights that virtual simulations allow the number of

physical prototypes necessary and testing costs to be reduced, shifting a relevant share of appraisal costs from the production phase to the virtual design phase, with overall lower costs. Resman et al. (2025) confirm that the adoption of the Digital Twin in a real industrial context has significantly improved operational efficiency, with direct effects on the reduction of verification and control costs.

Regarding prevention costs, the available evidence supports the logic according to which Quality 4.0 technologies increase the intensity of preventive activities, through continuous monitoring, predictive analytics, and virtual simulation, but reduce their unit cost through automation and data integration. Psarommatis et al. (2024) show that many ZDM implementations involve an increase in preventive investments, compensated by significantly superior reductions in failure costs. Indra et al. (2025) confirm that a prevention-oriented strategy has reduced total quality costs by 84.1%, with improvement of conformity from 96.11% to 99.75%.

5.4. Quality 4.0 and Hidden Quality Costs

Among the various components of the CoPQ, hidden quality costs represent the most difficult category to analyze and quantify. By definition, such costs encompass economic consequences of poor quality that do not result directly visible in traditional accounting systems: loss of commercial opportunities, deterioration of corporate reputation, reduction of customer satisfaction and loyalty, inefficiencies in organizational learning, and sub-optimization of resource utilization. Campanella (1999) and Sower et al. (2007b) highlight that these hidden costs can represent a significant share of real CoPQ, often much higher than the visible costs recorded in management systems.

One of the main contributions of Quality 4.0 technologies to the reduction of hidden quality costs concerns the improvement of operational visibility. Thomas (2024), analyzing the economic value of Digital Twins, highlights that a relevant part of the value generated by this technology derives from the reduction of operational uncertainty and from the greater capacity to identify and quantify qualitative risks that previously remained hidden. IoT systems, through the continuous collection of process data, allow inefficiencies and ineffective resource utilization that were traditionally not measured to be made visible (Liu et al., 2022; Santos et al., 2021; Mourtzis et al., 2018).

Fukuzawa et al. (2022) show, through an analysis of four Japanese companies, how investments in IoT systems have produced benefits that extend beyond operational metrics, influencing customer satisfaction and relationships with suppliers. Alkhatib et al. (2025) propose an integrated structure that allows quality to be monitored continuously, making visible problems that previously manifested only through post-sales claims or customer loss. Psarommatis et al. (2024) highlight that the most advanced ZDM implementations contribute not only to the reduction of measurable defects, but also to the improvement of customer quality perception, with positive effects on loyalty and commercial opportunities.

Despite this evidence, the hidden quality costs category presents the greatest limitations from an empirical standpoint. The difficulty of quantification, the dependence on contextual factors, and the lack of standardized measurement systems make the evaluation of the impact of Quality 4.0 technologies on this category complex. Schiffauerova & Thomson (2006) and Sower et al. (2007b) highlight that many organizations do not dispose of the necessary instruments to identify and measure these costs, limiting the availability of relevant empirical data.

5.5. Evidence from Integrated Quality 4.0 Implementations

The preceding sections have analyzed the impact of Quality 4.0 technologies on the different CoPQ categories by considering them separately, in coherence with the structure of the PAF model. However, one of the most recurring indications in recent literature concerns the systemic nature of the digital transformation of quality: the most significant benefits do not emerge from the isolated use of a single technology, but from the integration of multiple technologies within a coherent digital ecosystem (Sony et al., 2022; Carvalho et al., 2021; Psarommatis et al., 2024).

Psarommatis et al. (2022, 2024) highlight that ZDM implementations that produce the most significant results in terms of defect reduction and associated costs are those that integrate monitoring capabilities (IoT), predictive analytics (Machine Learning), and automated response (automation systems). Alkhatib et al. (2025) confirm this logic: the implemented PMQ framework is not limited to a single technological instrument, but integrates sensors, predictive algorithms, and control systems in a coherent architecture that acts simultaneously on multiple levels of the production system.

Thomas (2024) highlights that the economic value of Digital Twins is amplified when these are integrated with IoT systems that feed the digital twin with real-time data and with ML algorithms that support qualitative decisions. This integration generates synergies among the operational capabilities of Observability (IoT), Predictability (ML), and Operational-Design Integration (Digital Twin), producing combined effects on the reduction of failure costs superior to the sum of the individual effects of single technologies.

The MES systems literature also supports this interpretation. Shojaeinasab et al. (2022) and Mantravadi et al. (2023) show how new-generation MES systems perform an integration function that amplifies the value of other Industry 4.0 technologies, allowing the centralization and contextualization of quality information coming from IoT sensors, automation systems, and predictive algorithms. Fischer et al. (2021) highlight how the adoption of advanced MES is associated with higher levels of digital maturity, correlated with better qualitative performance and a greater capacity to reduce the different CoPQ categories.

Mufato Reis et al. (2024) underline that the effectiveness of Industry 4.0 technologies in quality cost

management depends on their integration with CoPQ measurement systems capable of transforming operational data into economically relevant information. Without this integration, digital technologies can improve operational performance without such improvements translating into documented reductions in CoPQ (Faciane et al., 2024; Schiffauerova & Thomson, 2006).

5.6. Synthesis of Empirical Findings and Implications for the Proposed Framework

The analysis of the empirical literature conducted in the preceding sections highlights a general conclusion of particular significance: Quality 4.0 technologies can contribute to the reduction of different CoPQ categories, but the mechanism through which such contribution is realized is mediated by the transformation of the organization's operational capabilities. The available evidence supports the plausibility of the causal chain proposed in the framework, Technologies → Operational capabilities → Quality Process Transformation → CoPQ Reduction but also highlights the existence of important contextual conditioning factors.

A first result concerns the distribution of evidence across the different CoPQ categories. The literature provides the most robust empirical support for internal failure costs: numerous studies document reductions in defects, reworks, scraps, and process variability (Psarommatis et al., 2022, 2024; Alkhatib et al., 2025; Farooq et al., 2017; Indra et al., 2025). The evidence regarding external failure costs results in significantly more limited. Hidden quality costs present the greatest empirical limitations, while recognizing that this category could contain a relevant share of the economic value generated by Quality 4.0.

The five operational capabilities identified in the framework receive differentiated empirical support from the literature. Observability capability (IoT) obtains the broadest and most coherent support: numerous studies documents how real-time continuous monitoring allows deviations to be identified before they translate into defects (Liu et al., 2022; Santos et al., 2021; Mourtzis et al., 2018; Fukuzawa et al., 2022; Kalsoom et al., 2021). Predictability (ML) is supported by studies that demonstrate how predictive algorithms allow faults and defects to be anticipated with high accuracy (Wuest et al., 2016; Alkhatib et al., 2025; Ayvaz & Alpay, 2021; Zonta et al., 2020; Jordan & Mitchell, 2015). Rapid Response (Automation) is documented in the ZDM literature (Mayr et al., 2018a, 2018b; Kamble et al., 2023). Operational-Design Integration (Digital Twin) is supported by Thomas (2024), Tao et al. (2019b), Li et al. (2023), and Resman et al. (2025). Coordination (MES) receives support from Fischer et al. (2021), Shojaeinasab et al. (2022), and Mantravadi et al. (2023).

A third element emerging from the analysis concerns the role of technological integration. The implementations that generate the broadest benefits are those that combine multiple technologies in a coherent ecosystem, suggesting that the synergies among operational capabilities amplify the individual

effects of each technology (Psarommatis et al., 2024; Thomas, 2024; Sony et al., 2022). This result directly supports the logic of the framework, which considers capability synergies as one of the central explanatory elements of the variability of results observed across different Quality 4.0 implementations.

From a theoretical standpoint, the existing literature tends to interpret the value of Quality 4.0 primarily through its effects on operational performance. The proposed framework suggests instead interpreting such value through the economic lens of CoPQ, identifying the cost categories specifically influenced by each operational capability. The analyzed empirical evidence supports this perspective, showing that CoPQ reduction is a plausible but non-automatic result of technological adoption: it depends on the organization's capacity to activate the appropriate operational capabilities and to integrate them in a coherent system (Teece et al., 1997; Winter, 2003; Warner & Wäger, 2019).

5.7. Limitations, gaps, and caveats in the available evidence

The analysis of the empirical literature conducted in the preceding sections has highlighted numerous pieces of evidence in support of the role of Quality 4.0 technologies in improving quality performance and in reducing various components of CoPQ. However, the same literature presents important methodological, conceptual, and empirical limitations that must be carefully considered in the interpretation of results and in the evaluation of the proposed framework.

The first limitation concerns the prevalence of studies focused on operational performance relative to economic consequences. Most of the analyzed publications measure indicators such as predictive accuracy, defect reduction, improvement of productive efficiency, or process optimization. For example, Alkhatib et al. (2025) report F1-score values above 0.98 and AUC close to 0.99; Farooq et al. (2017) document a defect reduction above 65%. Although such results constitute significant evidence of operational improvement, the connection between operational improvement and economic reduction of CoPQ is often assumed or discussed conceptually rather than measured empirically. Mufato Reis et al. (2024) underlines the necessity of models capable of translating operational information into economic knowledge.

A second limitation concerns the non-uniform distribution of evidence across CoPQ categories. A third limitation concerns the prevalence of studies focused on single technologies: as highlighted by Sony et al. (2022) and Psarommatis et al. (2024), the value of digital transformation often emerges from the integration among different system elements rather than from the isolated use of a single technology. A fourth limitation concerns the scarcity of longitudinal studies and the strong sectoral concentration, automotive, electronics, and aerospace, which could not be representative of the entire manufacturing landscape.

Particularly relevant for the present thesis is the limited availability of explanatory models that describe

the causal mechanisms between digital technologies and economic results. This observation represents the main gap identified by systematic research: the available evidence suggests that the economic value of Quality 4.0 does not derive directly from the technology, but from its capacity to modify the way in which organizations observe, predict, coordinate, and control quality processes. The proposed framework constitutes an attempt to fill this gap, proposing a conceptual structure that makes such causal mechanisms explicit and that offers a theoretical basis for future empirical validation activities (Sony et al., 2020; Antony et al., 2022; Teece et al., 1997; Winter, 2003).

Table 12. PRISMA 2020 Bibliographic Portfolio: Studies Included in the Systematic Literature Review (n = 84)

Nº	Title	Author(s)	Journal / Source	Year	Notes / Contribution to Framework	Topic
1	Essential Ingredients for the Implementation of Quality 4.0	Sony, Antony & Douglas	The TQM Journal	2020	Identifies the essential ingredients for Quality 4.0 implementation; main theoretical basis of the proposed framework.	Quality 4.0
2	A Systematic Review of Quality 4.0	Sony, Antony & McDermott	Int. J. Quality & Reliability Mgmt.	2022	Systematic review on definitions, technologies, and challenges of Quality 4.0; support for technology selection.	Quality 4.0
3	Quality 4.0: An Overview	Carvalho et al.	Procedia Computer Science	2021	Structured overview of Quality 4.0 technologies and impact on quality management systems.	Quality 4.0
4	Quality 4.0 Technologies and Readiness Factors in the Entire Value Flow	Salimbeni, Redchuk & Rousserie	Production & Manufacturing Research	2023	Analyzes organizational and technological factors of Quality 4.0 adoption along the value chain.	Quality 4.0
5	Quality 4.0 Conceptualization and Theoretical Understanding	Antony, McDermott, Sony & Furterer	The TQM Journal	2022	Develops the theoretical foundations of Quality 4.0; justifies the capability-based approach of the framework.	Quality 4.0
6	Quality 4.0 Conceptualization: A Global Exploratory Study	Sony, Antony & McDermott	The TQM Journal	2020	Global exploratory study that defines the concept of Quality 4.0 and its operational dimensions.	Quality 4.0

7	Empirical and Conceptual Review of Quality 4.0	Sony, Antony, McDermott & Garza-Reyes	Int. J. Quality & Reliability Mgmt.	2022	Empirical and conceptual review of Quality 4.0; supports integration with CoPQ.	Quality 4.0
8	Quality 4.0: Big Data Challenges in Manufacturing	Escobar, McGovern & Morales-Menendez	J. Intelligent Manufacturing	2022	Examines big data challenges for Quality 4.0; supports Predictability capability.	Quality 4.0 / Big Data
9	Quality 4.0: Let's Get Digital	Radziwill	Quality Progress	2018	Introduces the Quality 4.0 paradigm and the shift to data-driven systems; conceptual reference of the framework.	Quality 4.0
10	Quality Management in the Industry 4.0 Era	Demartini & Tonelli	Int. J. Productivity and Quality Mgmt.	2018	Analyzes the evolution of Quality Management in the Industry 4.0 era; basis for process transformation.	Quality 4.0
11	Building Dynamic Capabilities for Digital Transformation	Warner & Wäger	Long Range Planning	2019	Explains how organizations develop dynamic capabilities in digital transformation; theoretical support.	Dynamic Capabilities
12	Dynamic Capabilities and Strategic Management	Teece, Pisano & Shuen	Strategic Management Journal	1997	Seminal article on dynamic capabilities; explains how technologies generate benefits through intermediate capabilities.	Dynamic Capabilities
13	Understanding Dynamic Capabilities	Winter	Strategic Management Journal	2003	Clarifies the role of capabilities as intermediate mechanisms between resources and results; supports causal logic.	Dynamic Capabilities

14	Business Models and Dynamic Capabilities	Teece	Long Range Planning	2018	Links dynamic capabilities to digital business models; reinforces the capability-based perspective.	Dynamic Capabilities
15	Predictive Maintenance System for Production Lines in Manufacturing	Ayvaz & Alpay	Expert Systems with Applications	2021	Demonstrates how IoT and ML enable predictive maintenance through real-time analysis; supports Predictability.	IoT / ML
16	Empowering IoT Predictive Maintenance with AI	Liu, Yu, Dillon, Rahayu & Mostafa	IEEE Trans. Industrial Informatics	2022	Highlights the IoT contribution to early anomaly detection and operational visibility; supports Observability.	IoT
17	An IoT-Based Monitoring System for Shop-Floor Control	Mourtzis, Milas & Vlachou	J. Computing and Information Science in Eng.	2018	Shows how IoT enables continuous process monitoring and real-time quality control.	IoT
18	Real-Time Monitoring Architectures for Industry 4.0	Santos, Rocha & Vale	Sensors	2021	Analyzes continuous monitoring architectures that improve observability and deviation detection.	IoT
19	Impact of IoT on Manufacturing Industry 4.0	Kalsoom et al.	Sustainability	2021	Systematic review on the impact of IoT in Industry 4.0 manufacturing; supports the Observability capability.	IoT / Industry 4.0
20	Metrics and Performance of IoT Investment: Exploratory Case Study	Fukuzawa, Takahashi, Inoue & Kondo	Int. J. Production Economics	2022	Analyzes four Japanese manufacturing companies; documents IoT impact on operational performance and hidden costs.	IoT

21	Software-Defined Industrial Internet of Things	Wan et al.	IEEE Access	2016	Examines industrial IoT architectures for data integration and connectivity; supports the infrastructural basis.	IoT
22	Machine Learning-Enabled Smart Industrial Automation Using IoT	Al Shahrani et al.	Sensors	2023	Demonstrates ML-IoT integration for intelligent quality automation; supports Observability and Predictability.	IoT / ML
23	Machine Learning in Manufacturing: Advantages, Challenges and Applications	Wuest, Weimer, Irgens & Thoben	Production & Manufacturing Research	2016	Review of ML applications in manufacturing; central for defect prediction and process optimization.	ML
24	Real-Time Quality Analytics in Smart Manufacturing Environments	Nguyen & Harrison	Int. J. Production Research	2022	Demonstrates the role of predictive techniques in quality control and data-driven decision-making.	ML
25	Deep Learning-Empowered Digital Twin for Welding Quality Inspection	Ji & Nor	Sensors	2023	Applies Digital Twin and Deep Learning to automated quality inspection in welding operations.	Digital Twin / ML
26	Machine Learning: Trends, Perspectives, and Prospects	Jordan & Mitchell	Science	2015	Reference article on ML trends; theoretical basis for Predictability capability in the framework.	ML
27	Deep Learning	LeCun, Bengio & Hinton	Nature	2015	Foundational contribution to deep learning; supports advanced ML applications for manufacturing quality.	ML

28	Detection of Micro-Defects on Metal Screw Surfaces Based on Deep CNN	Song et al.	Sensors	2018	Applies convolutional neural networks to automated inspection; highlights reduction of inspection costs.	ML
29	Industrial AI for Industry 4.0-Based Manufacturing Systems	Lee, Davari, Singh & Pandhare	Manufacturing Letters	2018	Examines industrial AI applications for Industry 4.0; supports Predictability and Rapid Response.	ML / AI
30	Data-Driven Methods for Quality Control and Process Improvement	Schmidt, Wang & Beetz	Procedia CIRP	2015	Data-driven methods for quality control in smart manufacturing environments; supports process transformation.	ML / Quality
31	Systematic Literature Review of ML Methods for Predictive Maintenance	Carvalho et al.	Computers & Industrial Engineering	2019	Systematic review of ML methods for predictive maintenance; connection with internal failure costs.	ML / Maintenance
32	Digital Twin: Mitigating Unpredictable Emergent Behavior in Complex Systems	Grieves & Vickers	Springer	2017	Foundational contribution that defines the Digital Twin and its role in process simulation and optimization.	Digital Twin
33	Digital Twin-Based On-Site Quality Assessment for Aero-Engine Assembly	Li, Zhao, Zhang et al.	J. Manufacturing Systems	2023	Proposes a Digital Twin system for quality assessment during assembly; supports Observability.	Digital Twin
34	Integrating Digital Twin Technology to Achieve Higher Operational Efficiency	Resman, Heraković & Debevec	Systems	2025	Provides empirical evidence on the impact of Digital Twins on operational efficiency and quality performance.	Digital Twin

35	Digital Twin: Enabling Technologies, Challenges and Open Research	Fuller, Fan, Day & Barlow	IEEE Access	2020	Review of Digital Twin enabling technologies; supports the Op.-Design Integration capability.	Digital Twin
36	Digital Twin and Big Data Towards Smart Manufacturing and Industry 4.0	Qi & Tao	IEEE Access	2018	Links Digital Twin and big data for smart manufacturing; supports the operational integration of the framework.	Digital Twin / Industry 4.0
37	Digital Twin in Industry: State-of-the-Art	Tao, Zhang, Liu & Nee	IEEE Trans. Industrial Informatics	2019	Review of the state of the art of industrial Digital Twin; theoretical basis for Op.-Design Integration.	Digital Twin
38	Digital Twin-Driven Product Design Framework	Tao et al.	Int. J. Production Research	2019	Proposes a Digital Twin-based framework for product design and quality by design.	Digital Twin
39	Characterising the Digital Twin: A Systematic Literature Review	Jones, Snider, Nassehi et al.	CIRP J. Manufacturing Science and Technology	2020	Systematic review of the Digital Twin; provides definitions and taxonomy relevant to the framework.	Digital Twin
40	Roles of Digital Twin in CPS-Based Production Systems	Negri, Fumagalli & Macchi	Procedia Manufacturing	2017	Examine the roles of Digital Twin in cyber-physical production systems; supports process simulation.	Digital Twin
41	Digital Twin in Manufacturing: A Categorical Literature Review	Kritzinger, Karner, Traar et al.	IFAC-PapersOnLine	2018	Classification of manufacturing Digital Twin literature; supports technology selection.	Digital Twin

42	AI-Based Decision Making Model for Digital Twin Engineering	Orlova	Future Internet	2022	Integrates AI and Digital Twin for decision support; reinforces the Op.-Design Integration capability.	Digital Twin / AI
43	Digital Twin of Intelligent Small Surface Defect Detection	Wu et al.	J. Manufacturing Science and Technology	2023	Digital Twin applies to surface defect inspection; demonstrates reduction of inspection costs.	Digital Twin / ML
44	Economics of Digital Twins in Manufacturing	Thomas	NIST Advanced Manufacturing Series	2024	Economic analysis of Digital Twin; highlights reduction of CoPQ and hidden costs.	Digital Twin / CoPQ
45	Data-Driven Smart Manufacturing	Tao, Qi, Liu & Kusiak	J. Manufacturing Systems	2018	Examines data-driven smart manufacturing; supports data-driven transformation of quality processes.	Industry 4.0 / Digital Twin
46	Manufacturing Execution Systems and Industry 4.0 Maturity	Fischer, Fuchs, Franke & Reinhart	Procedia CIRP	2021	Demonstrates how MES enable information integration, process visibility, and operational coordination.	MES
47	Application of MES/MOM for Industry 4.0 Supply Chains	Mantravadi, Srail & Møller	Computers in Industry	2023	Analyzes the role of MES in synchronizing production processes and managing quality information.	MES
48	Intelligent MES for Industry 4.0: A Systematic Review	Shojaeinasab, Ghomi, Fakhrzad & Vaziri	J. Manufacturing Systems	2022	Systematic review of intelligent MES architectures and their contribution to quality control.	MES

49	Next-Generation MES: How Important Is MES for Industry 4.0?	Mantravadi & Møller	Procedia Manufacturing	2019	Examine the characteristics of next-generation MES and their importance for Industry 4.0.	MES
50	Integration of PLM, MES, and ERP to Optimize Engineering and Production	Avvaru, Bruno, Chiabert et al.	IFIP Advances in ICT	2020	Analyzes PLM-MES-ERP integration; supports the Coordination capability of the framework.	MES
51	Impact of MES on OEE in Smart Manufacturing	Bobeica, Popescu, Ichim & Angelescu	Advances in Electrical and Computer Engineering	2025	Highlights the impact of MES on OEE in smart manufacturing environments.	MES
52	Intelligent Defect Detection and Classification in MES with IoT	Ranganathan et al.	Proc. Int. Conf. on Smart Technologies	2024	Demonstrates intelligent defect detection through MES-IoT integration.	MES / IoT
53	Digital Quality Management and Intelligent Inspection in Smart Manufacturing	Kamble, Gunasekaran & Sharma	Computers & Industrial Engineering	2023	Examines automated inspection and quality control systems; highlights reduction of inspection costs.	Automation / Quality
54	Smart Manufacturing	Kusiak	Int. J. Production Research	2018	Defines smart manufacturing and the role of automation in waste and defect reduction.	Industry 4.0 / Automation
55	Smart Manufacturing: Characteristics, Technologies, and Enabling Factors	Mittal, Khan, Romero & Wuest	Proc. IMechE Part B	2019	Characterizes smart manufacturing and enabling factors; supports understanding of automation.	Industry 4.0 / Automation
56	Zero-Defect Manufacturing: Approach for Higher Manufacturing Sustainability	Psarommatis, Sousa, Mendonça & Kiritsis	Int. J. Production Research	2022	Illustrates how predictive and preventive mechanisms allow defect reduction and reliability improvement.	Zero Defect Manufacturing

57	Zero Defect Manufacturing in 2024: A Holistic Literature Review	Psarommatis, May, Dreyfus & Kiritsis	Computers & Industrial Engineering	2024	Comprehensive review of defect prevention strategies supported by Industry 4.0 technologies.	Zero Defect Manufacturing
58	Zero Defect Manufacturing: State-of-the-Art and Future Directions	Psarommatis, May, Dreyfus & Kiritsis	Int. J. Production Research	2020	Provides the conceptual baseline for Zero Defect Manufacturing; supports the preventive logic.	Zero Defect Manufacturing
59	ZDM by Detection and Avoidance Using Industry 4.0 Technologies	Mayr, Weigelt, Kühl et al.	Procedia CIRP	2018	Shows how Industry 4.0 technologies support real-time defect detection and prevention.	Zero Defect Manufacturing
60	ZDM by Detection and Avoidance Using ML and Edge Computing	Mayr, Weigelt, Kühl et al.	Procedia CIRP	2018	Applies ML and edge computing to ZDM; highlights reduction of internal failure costs.	Zero Defect Mfg. / ML
61	Quality 4.0 PMQ Framework in Automotive Manufacturing	Alkhatib, Al-Mutairi, Alenezi & Alshammari	Computers & Industrial Engineering	2025	Empirical case of the PMQ framework in an automotive context; F1-score >0.98, AUC ≈0.99. Central evidence of Chapter 5.	Quality 4.0 / CoPQ
62	Industry 4.1: Intelligent Manufacturing with Zero Defects	Cheng	Wiley-IEEE Press	2022	Proposes the Industry 4.1 paradigm oriented toward zero defectiveness; links Industry 4.0 and perfect quality.	Zero Defect / Industry 4.0
63	Cost of Quality: Evaluating Cost-Quality Trade-offs for Inspection Strategies	Farooq, Kirchain, Novoa & Araujo	Int. J. Production Economics	2017	Explicitly quantifies trade-offs between appraisal costs and failure costs. Defect reduction >65%, +10% productivity.	CoPQ

64	Quality Costs and Industry 4.0: Inspection Strategy Modelling	Mufato Reis, Dall-Orsoletta et al.	Int. J. Advanced Manufacturing Technology	2024	Directly links Industry 4.0 technologies to economic quality management and inspection strategies.	CoPQ / Industry 4.0
65	Reducing the Costs of Poor Quality: A Manufacturing Case Study	Faciane	Doctoral Study – Walden University	2018	Case study on CoPQ; supports the economic framing of the framework.	CoPQ
66	CoPQ in Manufacturing: A Systematic Review	Faciane et al.	Quality Engineering	2024	Systematic review of CoPQ categories and measurement approaches in manufacturing contexts.	CoPQ
67	Quality Cost Flows in Manufacturing Companies	Bris, Cermakova & Molnar	Acta Logistica	2022	Analyzes quality cost flows in manufacturing companies; empirical basis for CoPQ measurement.	CoPQ
68	Cost of Quality Applications in Mature Quality Management Systems	Sower	Quality Management Journal	2007	Examines CoQ utilization in mature systems; provides benchmarks for CoPQ measurement.	CoPQ
69	Cost of Quality and Its Relationship to Quality System Maturity	Sower, Quarles & Broussard	Int. J. Quality & Reliability Management	2007	Highlights the relationship between quality system maturity and CoQ utilization; basis for economic measurement.	CoPQ
70	A Review of Research on Cost of Quality Models and Best Practices	Schiffauerova & Thomson	Int. J. Quality & Reliability Management	2006	Foundational review on Cost of Quality models; supports the PAF classification used in the framework.	CoPQ

71	Empirical Validation of Prevention-Focused Quality Cost Management	Indra, Yudoko & Mulyono	Cogent Business & Management	2025	Empirically validates prevention-focused quality cost management: –84.1% CoPQ, quality 99.75%.	CoPQ
72	Industry 4.0 Technologies: Implementation Patterns in Manufacturing	Frank, Dalenogare & Ayala	Int. J. Production Economics	2019	Examines implementation patterns of Industry 4.0 technologies; supports technology selection.	Industry 4.0
73	Classification of Industry 4.0 for Total Quality Management	Baran & Korkusuz Polat	Sustainability	2022	Classifies Industry 4.0 technologies in relation to TQM; basis for Quality 4.0-Industry 4.0 integration.	Industry 4.0 / Quality 4.0
74	Industry 4.0 Technologies in Manufacturing: A Systematic Literature Review	Chiarini	Int. J. Production Research	2021	Systematic review of Industry 4.0 technologies in manufacturing systems; supports technology selection.	Industry 4.0
75	Design Principles for Industrie 4.0 Scenarios	Hermann, Pentek & Otto	Proc. 49th HICSS	2016	Defines design principles for Industry 4.0; provides the conceptual basis for implementation.	Industry 4.0
76	Industry 4.0: State of the Art and Future Trends	Xu, Xu & Li	Int. J. Production Research	2018	Review of the state of the art of Industry 4.0; frames the selected technologies within the paradigm.	Industry 4.0
77	Industry 4.0 and Industry 5.0: Inception, Conception, and Perception	Xu, Lu, Vogel-Heuser & Wang	J. Manufacturing Systems	2021	Analyzes the evolution from Industry 4.0 to Industry 5.0; supports the evolutionary perspective of Quality Management.	Industry 4.0

78	Smart Factory of Industry 4.0: Key Technologies, Application and Challenges	Chen, Wan, Shu et al.	IEEE Access	2018	Examines the key technologies of the smart factory; supports understanding of enabling technologies.	Industry 4.0
79	A Cyber-Physical Systems Architecture for Industry 4.0-Based Manufacturing	Lee, Bagheri & Kao	Manufacturing Letters	2015	Proposes a CPS architecture for Industry 4.0; supports understanding of the technological infrastructure.	Industry 4.0
80	Understanding Digital Transformation: A Review and Research Agenda	Vial	J. Strategic Information Systems	2019	Review of digital transformation; provides the theoretical context for Quality 4.0 technology adoption.	Digital Transformation
81	Digital Transformation: A Multidisciplinary Reflection and Research Agenda	Verhoef et al.	J. Business Research	2021	Analyzes digital transformation from multiple perspectives; supports the managerial framing of the framework.	Digital Transformation
82	Smart Maintenance: A Research Agenda for Industrial Practice	Bokrantz, Skoogh, Berlin et al.	J. Manufacturing Technology Mgmt.	2020	Defines the research agenda for smart maintenance; links predictive maintenance with failure costs.	IoT / Maintenance
83	Predictive Maintenance in the Context of Industry 4.0	Zonta, da Costa, da Rosa Righi et al.	Computers & Industrial Engineering	2020	Examines predictive maintenance in the Industry 4.0 context; supports the Predictability capability.	IoT / ML / Maintenance
84	Integrating Six Sigma and Lean Management for Enhanced Quality Management	Abualsauod	J. Engineering Research	2026	Integrates Six Sigma and Lean for quality improvement; supports the perspective of quality as an integrated system.	Quality Management

Note: Complete bibliographic references are reported in the References section. Compiled by the author based on the systematic literature review.

6. Conclusions and Future Work

The present research set out to fill a specific gap in Quality 4.0 literature: although a growing number of studies documented the applications of digital technologies in manufacturing systems and their potential operational benefits, the understanding of the mechanisms through which such technologies contribute to the reduction of CoPQ remained fragmented and theoretically unresolved. The objective was not to demonstrate the efficacy of individual technologies, but to build an explanatory model capable of describing the causal chains that connect the adoption of Quality 4.0 to the economic reduction of poor quality in manufacturing systems.

The research questions were addressed as follows. RQ1 clarified that the digitalization of quality transforms manufacturing processes through five fundamental changes: from manual monitoring to continuous real-time control, from reactive management to anticipatory forecasting, from slow corrective intervention to autonomous response, from physical experimentation to virtual simulation, and from functional fragmentation to informational integration. RQ2 identified five operational capabilities as intermediate mechanisms: Observability (IoT), Predictability (Machine Learning), Rapid Response (Automation), Operational-Design Integration (Digital Twin), and Coordination (MES). RQ3 suggested that each capability is expected to influence specific CoPQ categories in a distinct way: internal and external failure costs, prevention and appraisal costs, hidden costs, and that the effects are significantly amplified when the capabilities operate in an integrated manner.

The main result of this research is a four-level mechanistic framework: Quality 4.0 Technologies → Operational Capabilities → Quality Process Transformation → CoPQ Reduction. The central conceptual contribution consists in the introduction of operational capabilities as an intermediate level of analysis, not yet systematically integrated in existing frameworks. This intermediate level explains an empirically observed but theoretically unresolved phenomenon: why organizations with similar technological investments obtain such diverse economic results. The value of Quality 4.0 does not derive from the availability of digital instruments, but from the organizational capacity to mobilize the operational capabilities that such instruments make possible.

The systematic review of the literature provided consistent, though indirect, support for the plausibility of the proposed relationships: the analyzed literature reports reductions in scraps, reworks, claims, and hidden costs in contexts where the capabilities were effectively activated. At the same time, the data show that the benefits depend on organizational maturity, on the integration of information systems, and on the availability of adequate competencies, not on technological adoption per se. The framework further contributes to bridging the divide between two traditionally separate streams of literature,

Quality 4.0, and CoPQ, proposing a unified structure that connects them through explicit causal relationships.

In conclusion, this thesis suggests that CoPQ reduction is not an automatic consequence of digitalization, but the result of a sequence of operational transformations that becomes comprehensible only by adopting a mechanistic perspective. The proposed framework does not quantify absolute benefits nor replace managerial judgment: it offers an instrument for reading the digital transformation of quality through the economic lens of CoPQ, orienting investment decisions toward the mechanisms that effectively generate value in manufacturing systems.

The research presents three main limitations. In the first place, the framework is theoretical-conceptual in nature: the proposed causal relationships are founded on the synthesis of existing literature and have not been validated with empirical data collected directly in corporate contexts. In the second place, the analysis focuses on five specific technologies, excluding other relevant digital instruments for manufacturing quality, such as blockchain, augmented reality, or edge computing. In the third place, the model was developed with reference to the manufacturing sector and its applicability to other contexts would require theoretical adaptations. Such limitations define the perimeter within which the results must be interpreted and orient the priority directions for future research.

6.1. Suggestions for further research

Among these directions, empirical validation represents the single most pressing priority, since the framework's practical value ultimately depends on confirming that the proposed causal mechanisms are held under real operating conditions. The first direction concerns the empirical validation of the framework through case studies conducted in real manufacturing contexts. Although all the proposed relationships are founded in existing literature, the model has not been verified with data collected directly in companies. Future research could analyze organizations that have adopted Quality 4.0 technologies to verify whether the identified causal pathways, and particularly the role of the five operational capabilities, find confirmation in practice, and to what extent the expected economic benefits manifest across the different CoPQ categories.

This validation could take multiple complementary forms: in-depth case studies of individual organizations, survey-based research across a larger sample of manufacturing firms, and quantitative analysis comparing CoPQ data before and after the introduction of Quality 4.0 technologies, each offering a different balance between depth of insight and generalizability of results.

A second opportunity concerns the quantification of the intensity of the proposed causal relationships. The framework identifies connections among technologies, capabilities, processes, and cost categories,

but does not measure their relative strength. Future studies could develop quantitative models to estimate the relative contribution of each capability to the reduction of the different CoPQ categories and to understand whether such effects vary as a function of the productive context.

A third line of research concerns the analysis of sectoral variations. The framework was developed with general reference to manufacturing systems, but it is plausible that the proposed causal mechanisms manifest differently in specific sectors, each characterized by specific cost structures, regulatory requirements, and qualitative criticalities. Sectoral applications of the framework could identify which capabilities assume greater relevance in determined contexts and evaluate the necessity of model adaptations.

From an economic standpoint, a particularly relevant direction concerns the development of methodologies for estimating the return on Quality 4.0 investments disaggregated by CoPQ category. One of the main limitations highlighted in managerial practice is the difficulty of economically justifying digital investments when the benefits are distributed across different cost categories and manifest over different time horizons. The proposed framework could constitute the theoretical basis for the construction of evaluation models capable of connecting specific technologies to measurable economic impacts, supporting more informed investment decisions.

Finally, a promising perspective consists in the integration of the framework with dynamic simulation instruments. Since the model describes relationships among variables that evolve over time, approaches based on System Dynamics, agent-based modelling, or organizational Digital Twins could be used to simulate how the benefits of Quality 4.0 develop over time and how different sequences of technological adoption influence the CoPQ reduction trajectory. Such developments could transform the framework from an interpretive instrument to a predictive one, significantly expanding its applicative value.

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