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# Hybrid Quality Management Systems: A New Architectural Approach for Smart Manufacturing

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## Abstract

The transformation toward smart manufacturing has exposed the limitations of traditional Quality Management Systems (QMS), which are often too rigid and reactive to meet the demands of modern, data-driven production environments. This study proposes a hybrid QMS architecture that integrates conventional quality assurance protocols with emerging digital technologies, including the Internet of Things (IoT), cloud computing, and modular microservices. Emphasizing adaptability, scalability, and real-time responsiveness, the hybrid framework is designed to meet the multifaceted quality requirements of Industry 5.0. The paper synthesizes case studies from advanced manufacturing settings and applies a theoretically grounded architectural framework to explore the integration of digital and traditional components. By bridging the gap between compliance-driven quality models and dynamic production ecosystems, the proposed hybrid QMS enables proactive, human-centric quality control while supporting technological evolution and operational scalability.

## Keywords
Hybrid QMS, Industry 5.0, Smart Manufacturing, Modular Architecture, IoT Integration, Cloud Computing, Quality Management Systems, Real-Time Monitoring, Adaptive Quality Control

## 1. Introduction
Background on Smart Manufacturing and Quality Management Systems (QMS)
Smart manufacturing represents a shift in industrial production, using real-time data, automation, and interconnected systems to enhance efficiency and responsiveness. The integration of cyber-physical systems (CPS), Internet of Things (IoT), and big data analytics has enabled factories to become autonomous and adaptive (Saadati & Barenji, 2023; Zhang et al., 2021). These capabilities require continuous, predictive quality control mechanisms rather than periodic inspections (Sony & Naik, 2020).Traditional Quality Management Systems (QMS) ensure product consistency and regulatory compliance. However, these systems were designed for static environments with slower production cycles. Their reliance on retrospective inspections makes them inadequate for smart manufacturing's dynamic operations (Zonnenshain & Kenett, 2020). As manufacturing becomes data-driven, quality systems must be dynamic, adaptable, and integrated with digital infrastructure.

### 1.1 Statement of the Problem
Despite their effectiveness, conventional QMS frameworks fall short in managing quality in fast-paced, data-intensive manufacturing environments. These systems lack flexibility, real-time responsiveness, and digital integration needed to address variability in smart production ecosystems. These disconnects between traditional quality methods and Industry 5.0 demands have created a need for an evolved quality paradigm that merges structured protocols with intelligent, digital capabilities.

### 1.2 Research Objectives
This study aims to:
1. Develop a hybrid QMS architecture that integrates traditional quality assurance methods with advanced digital technologies.
2. Identify key technological components and integration strategies essential for scalable and flexible quality management in smart manufacturing.
3. Evaluate the operational and strategic implications of hybrid QMS adoption in real-world industrial contexts.

### 1.3 Research Questions
1. How can traditional QMS practices be integrated with smart manufacturing technologies to form an effective hybrid architecture?
2. What are the essential components required to design a scalable, modular hybrid QMS?
3. In what ways does a hybrid QMS enhance operational responsiveness and quality control in smart manufacturing?

## 2. Theoretical Framework
### 2.1 Hybrid Systems Theory in Quality Management
Hybrid systems theory integrates conventional and digital quality management practices through a dual-structure framework where traditional protocols coexist with adaptive digital tools (Nguyen et al., 2023). This model combines structured quality control with real-time data analytics. By bridging procedural systems and technology-enabled processes, hybrid QMS systems provide stability and agility.

The theory emphasizes human-machine collaboration aligned with Industry 5.0 principles. Humans provide nuanced decision-making while automated systems handle data-intensive tasks. This integration enhances operational resilience and quality assurance (Sony & Naik 2020).

### 2.2 Principles of Modularity, Scalability, and Interconnectivity
The foundation of a sustainable and adaptive hybrid Quality Management System (QMS) lies in three interdependent architectural principles: **modularity**, **scalability**, and **interconnectivity**. These principles serve as the structural logic guiding the design and evolution of digital quality systems.

- Modularity ensures that individual QMS components—such as monitoring, reporting, and analytics—function independently and can be upgraded or replaced without affecting the overall system. This compartmentalization enables rapid adoption of new technologies and reduces downtime during transitions or updates.
- Scalability refers to the system's capacity to grow in tandem with operational demands. Whether expanding production volume or increasing process complexity, a scalable QMS adjusts its monitoring and analytics functions without compromising performance or compliance.
- Interconnectivity enables continuous, real-time data flow between IoT devices, cloud infrastructures, and legacy systems. By maintaining synchronized communication across platforms, hybrid QMS delivers integrated, data-rich insights that inform timely and holistic quality decisions (Hieu, 2023).

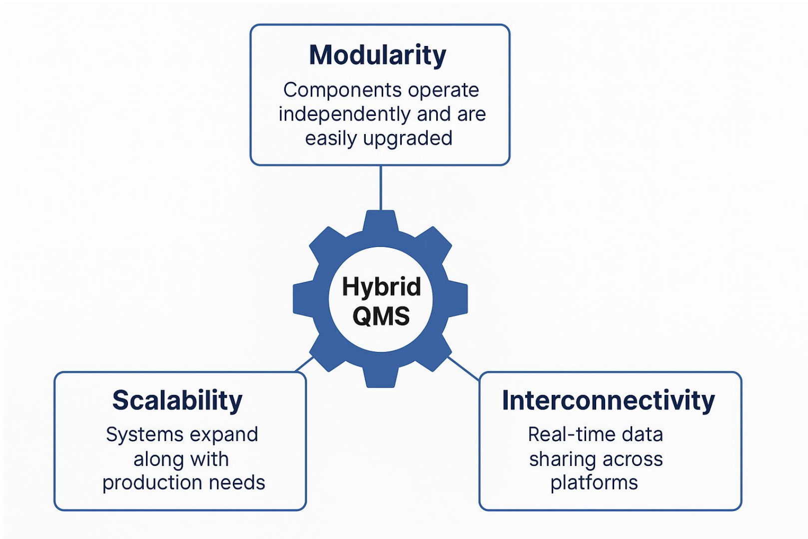


Figure 1. Core Architectural Principles of Hybrid QMS

This diagram shows the three foundational principles of Hybrid Quality Management Systems: modularity, scalability, and interconnectivity. Modularity enables independent component updates; scalability allows system expansion with production needs; and interconnectivity ensures data sharing across digital and legacy platforms. These principles support adaptive, sustainable quality assurance aligned with Industry 5.0 objectives.

### 2.3 Frameworks for Digital-Traditional Integration

Implementing a hybrid Quality Management System (QMS) requires integrating digital technologies with traditional governance mechanisms. A layered architectural framework is an effective approach to achieve this integration, enabling system modularity, interoperability, and traceability across physical and digital domains.

#### 2.3.1 The Layered Architecture Model

The Layered Architecture Model segments the hybrid QMS into functional layers that interact to support real-time quality assurance while maintaining compliance with standards. Each layer serves a distinct role in the data lifecycle, from infrastructure to decision-making.

As shown in Figure 2.2, the layers are organized as follows:

1. Infrastructure Layer
   Comprising cloud platforms, microservices, and middleware, this layer provides the foundational digital backbone for system connectivity, data storage, and application hosting.
2. Data Acquisition Layer
   This layer includes IoT sensors, edge devices, and AR/VR inputs that collect real-time operational data from the production environment.
3. Data Processing Layer
   Machine learning algorithms, anomaly detection tools, and analytical dashboards reside here, transforming raw data into quality insights.
4. Human Oversight Layer
   Quality inspectors, supervisors, and feedback loops operate in this layer, ensuring that machine-generated outputs are validated and interpreted with human expertise.
5. Governance & Standards Layer
   This layer embeds regulatory frameworks such as ISO 9001, SOPs, and audit protocols, ensuring that both digital and manual activities adhere to compliance requirements.
6. Decision/Action Layer
   The final layer represents the point of intervention, where validated insights trigger corrective or preventive actions. Feedback mechanisms loop back into the system, continuously refining decision logic, models, and standards.

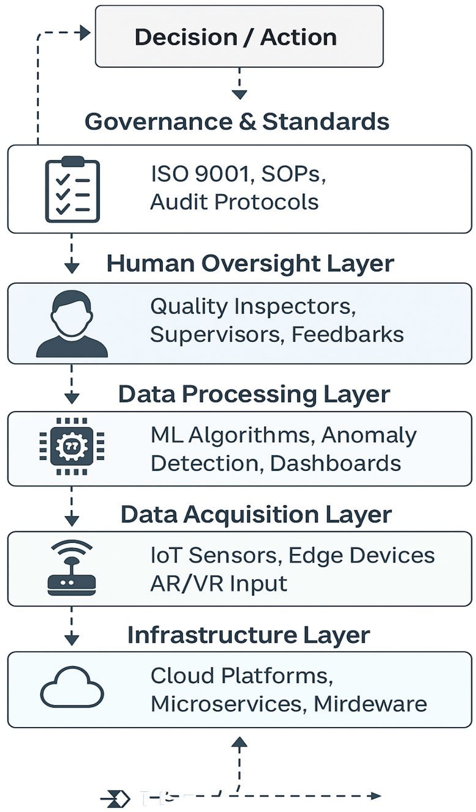


Figure 2. Layered Hybrid QMS Architecture Integrating Digital and Traditional Domains

This figure shows a layered model for hybrid Quality Management Systems, integrating cloud infrastructure, IoT data, AI processing, and human oversight under ISO-compliant governance. The model supports interoperability and human-in-the-loop control essential to Industry 5.0.

This layered model supports key design principles—modularity, scalability, and interconnectivity—by providing a structured approach to hybrid QMS design. It combines real-time digital responsiveness with traditional oversight for adaptive quality control in Industry 5.0 environments.

### 2.3.2 Integration Considerations

To ensure a resilient and compliant hybrid QMS, several integration best practices should be embedded into the architecture:

- Data Validation Protocols
  Automated cross-checks and audit trails to verify data integrity across all layers.
- Cybersecurity Frameworks
  Role-based access control, encryption, and intrusion detection systems to secure data movement and platform interfaces.
- Hybrid Audit Mechanisms
  Blended approaches that incorporate both digital logs and manual verification procedures to satisfy regulatory scrutiny.

## 3. Research Methodology

The methodology focuses on analyzing design, operation, and effects of Hybrid Quality Management Systems (Hybrid QMS) within smart manufacturing. Instead of gathering primary data through surveys or interviews, the research uses a mixed-methods conceptual framework combining literature review and case study synthesis.

### 3.1 Research Design
The study employs a mixed-methods design combining theoretical analysis with empirical insights from literature and case studies. The qualitative component conducts thematic analysis of reports and articles to identify integration strategies and benefits of hybrid QMS. The quantitative component synthesizes performance data including defect rates and system metrics from published cases. This approach bridges conceptual frameworks with practical implementations while enabling analytical depth.

### 3.2 Data Collection Sources
Data were collected from three primary sources:
- Peer-reviewed journals (2018–2024): Targeted literature in quality engineering, smart manufacturing, Industry 5.0, and digital systems integration.
- White papers and industry reports: From global manufacturers and technology providers detailing hybrid QMS deployments.
- Case studies in advanced manufacturing: Particularly those involving IoT-enabled, cloud-integrated quality systems in electronics, automotive, and pharmaceutical sectors.

Selection criteria included: (a) evidence of digital-traditional integration in QMS, (b) availability of performance metrics, and (c) system architecture transparency.

### 3.3 Analytical Approach
The analysis follows three stages:
1. Thematic synthesis: Identify recurring architectural patterns, integration strategies, and implementation challenges across sources.
2. Cross-case comparison: Contrast Hybrid QMS outcomes by sector and technology profile to identify enabling factors and constraints.
3. Framework validation: Compare emerging patterns against the theoretical model proposed in Section II to assess conceptual alignment.

This approach allows triangulation of evidence, improving reliability and providing a multi-dimensional view of Hybrid QMS effectiveness in varying industrial settings.

### 3.4 Tools and Techniques
To structure the evaluation:
- Matrix mapping was used to align functional QMS components with performance indicators (e.g., real-time responsiveness, quality variance reduction).
- Qualitative coding captured organizational insights on implementation challenges (e.g., workforce resistance, system complexity).
- Descriptive statistics from case reports (e.g., cycle time improvement percentages) were normalized and compared across industry types.

Together, these tools supported the formulation of a robust, evidence-based perspective on hybrid QMS design and performance.

## 4. Literature Review
This section synthesizes existing scholarship and industry insights related to traditional QMS limitations, technological advancements in smart manufacturing, and the emergence of hybrid QMS architectures. The literature review serves to contextualize the research within the broader field of quality engineering and Industry 5.0 transformations.

### 4.1 Limitations of Traditional QMS Frameworks
According to Zonnenshain and Kenett (2020), traditional Quality Management Systems emphasize standardization, compliance, and procedural audits. While effective in stable production environments, they are increasingly inadequate in dynamic, technology-driven contexts. Sony and Naik (2020) explain that conventional QMS often rely on post-process inspections, lack responsiveness, and fail to incorporate real-time data. This static approach limits the capacity to manage variability and quality risks inherent in smart manufacturing.

### 4.2 Smart Manufacturing Technologies and Implications for QMS
The convergence of IoT, artificial intelligence (AI), and cyber-physical systems has reshaped manufacturing by enabling autonomous decisions and real-time feedback (Balasubramanian & Scholar Ii, 2023). Czeczot et al. (2023) discuss how IoT enables data gathering from production lines, while AI aids in pattern recognition and anomaly detection. These functionalities shift quality management from inspection to proactive control. Cloud platforms improve scalability, while edge computing ensures responsiveness. These advances push QMS to evolve into integrated, predictive systems. A hybrid model is necessary to harness these technologies while maintaining compliance.

### 4.3 IoT, Cloud, and Modular QMS Architectures
The integration of Internet of Things (IoT) and cloud technologies into Quality Management Systems (QMS) is essential for real-time quality assurance, as highlighted by Zhang et al. (2021). IoT sensors monitor parameters like temperature and pressure, while cloud platforms enable centralized data processing. According to Kohl et al. (2021), modular QMS architectures facilitate technology incorporation without complete system overhaul. This modularity extends system lifespan and enhances decision-making through cloud analytics, making hybrid QMS suitable for dynamic manufacturing environments.

### 4.4 Emergence of Hybrid QMS and Industry 5.0 Context
Ali et al. (2024) show that hybrid QMS models aligned with Industry 5.0 combine digital tools with human oversight. These systems integrate compliance mechanisms with AI and IoT, establishing new quality management standards. Their research reveals key features including layered architecture, real-time responses, predictive interventions, and continuous improvement for manufacturing success.

As highlighted by Ali et al. (2024) and Czeczot et al. (2023), hybrid QMS systems align automation with human decision-making for compliance and flexibility. With Industry 5.0 emphasizing sustainability and human-machine collaboration, hybrid QMS are becoming key drivers of forward-thinking manufacturing. The literature reviewed provides strong backing for the proposed model, emphasizing its importance in the evolving smart manufacturing environment. This model is essential for those aiming to lead in future manufacturing.

## 5. Components of Hybrid QMS Architecture
A hybrid Quality Management System (QMS) integrates traditional frameworks with digital tools and interfaces. These elements enable data exchange and adaptable management in smart manufacturing. The system combines IoT, cloud computing, and microservices with intelligent middleware to support real-time monitoring and automation, achieving Industry 5.0's goals of resilience and human-centered collaboration.

### 5.1 Core Traditional Quality Components
Traditional Quality Management System (QMS) elements—inspection routines, compliance audits, and corrective actions—remain fundamental to hybrid architectures, as affirmed by Nguyen et al. (2023). These mechanisms ensure process discipline and operational consistency. Within their framework, traditional controls serve as benchmarks for assessing real-time data analytics and digital interventions.
Furthermore, audits validate both human-driven and automated quality processes (Filz et al., 2024). Core governance instruments like documentation standards, quality manuals, and control charts are retained in hybrid QMS models to ensure procedural accountability and transparency.

### 5.2 Digital Components: IoT, Cloud, and Microservices
Three digital technologies are foundational to the performance and scalability of hybrid Quality Management Systems (QMS), as emphasized by Liu et al. (2023).

- IoT (Internet of Things): Sensors and smart devices across production enable real-time data capture. This supports predictive maintenance and deviation detection, thereby enhancing operational foresight.
- Cloud Computing: Cloud-based infrastructures enable centralized data storage and analytics while allowing quality teams at different sites to access synchronized data. Bajic et al. (2023) argue that this architecture supports collaborative decision-making and scalable analytics.
- Microservices Architecture: By decoupling quality functions into services—such as defect classification, data visualization, and reporting—microservices allow flexible system enhancements without disrupting the architecture (El Akhdar et al. 2024).

Collectively, these digital enablers form the technological backbone of modern hybrid QMS, ensuring both responsiveness and adaptability in fast-paced manufacturing environments.

### 5.3 Integration and Interfacing Layers

Coordination between traditional and digital components requires interfacing layers. Patera et al. (2022) describe this as middleware facilitating bidirectional data flow between IoT devices, cloud analytics, and legacy systems.
Key elements include:

- Data Interfaces: Real-time conversion of sensor outputs into quality indicators.
- Communication Protocols: Standards such as MQTT and OPC UA ensure secure and synchronized communication among distributed components.
- Middleware Solutions: As noted by Anthony Jnr et al. (2021) and Giebler et al. (2021) respectfully, platforms like enterprise service buses (ESBs) and data lakes allow centralized integration and dynamic routing of quality data.

These layers ensure system interoperability and enable the hybrid QMS to function cohesively. By aligning components, hybrid QMS offers an adaptive framework for real-time monitoring, contextual decision-making, and continuous improvement aligned with Industry 5.0 aspirations.

## 6. Modularity and Scalability in Hybrid QMS Design

To meet the demands of dynamic, digitally enabled manufacturing, Hybrid Quality Management Systems (QMS) must be designed around the foundational principles of **modularity** and **scalability**. These principles provide the structural flexibility and operational extensibility required to evolve quality systems in step with Industry 5.0's emphasis on collaboration, resilience, and continuous improvement.

### 6.1 Importance of Modularity in QMS Flexibility

Modularity enables QMS components to function as interoperable, upgradable modules. As Golovianko et al. (2023) emphasize, hybrid QMS architectures benefit from compartmentalized units—such as monitoring, defect classification, or reporting—that can be enhanced without disrupting the broader system. Such modular interfaces (see Figure 6.1) facilitate digital tool integration, including IoT sensors and AI analytics, with minimal interruption to operations (Balasubramanian & Scholar Ii, 2023; Zdravković et al., 2022). This design accelerates deployment cycles and supports targeted innovation within quality domains.

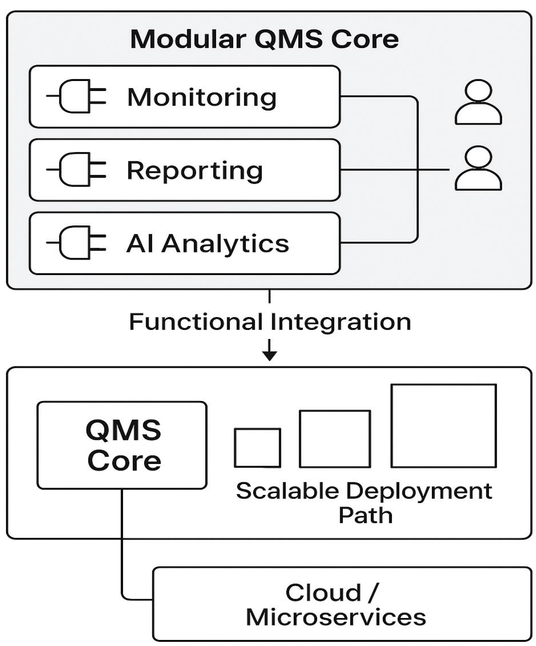


Figure 3. Modularity and Scalability in Hybrid QMS Design

This figure shows how plug-in components like monitoring, analytics, and reporting interface with a QMS engine, enabling independent updates without disrupting operations. The architecture supports scalable deployment across units via reusable digital blocks in cloud and microservice infrastructure. Modularity enables role-based access and functional autonomy. Mishra and Ray (2022)and Çelik (2024) highlight that decentralized teams can manage specific QMS modules independently. This distributed control improves collaboration and enables rapid response to quality challenges.

### 6.2 Scalability Requirements in Smart Manufacturing

Scalability ensures hybrid QMS architecture can expand with production volumes across locations. Smart manufacturing requires quality systems that can grow without performance degradation.

Both Oye et al. (2024) and Pham et al. (2023) note that cloud databases and microservice architectures enable scalable QMS deployment. These platforms allow systems to scale horizontally and vertically without reconfiguration.

As shown in Figure 6.1, scalable deployment uses reusable building blocks representing quality functionality that can be replicated—providing centralized oversight and local autonomy. According to Sony and Naik (2020), this ensures quality processes evolve while maintaining responsiveness. Arora (2023) emphasize that cloud-based QMS platforms enable real-time data synchronization across sites, supporting integrated decisions while respecting local processes.

### 6.3 Strategic Implications

Together, modularity and scalability create a resilient architecture for hybrid QMS—one that adapts to organizational change, integrates emerging technologies, and supports distributed teams across operational contexts. These principles are not only technical enablers but **strategic imperatives** for Industry 5.0-ready manufacturing systems.

### 6.4 Case Illustrations of Modular and Scalable Hybrid QMS

Recent research has emphasized the effective adoption of modular and scalable Hybrid Quality Management Systems (QMS) across different sectors:

- Electronics Manufacturing: Research by Elkateb et al. (2024) introduces a predictive maintenance system using machine learning algorithms and IoT-enabled devices in the textile sector. This system categorizes machine stoppages in real-time, highlighting the effectiveness of modular and scalable QMS in manufacturing settings.
- Pharmaceutical Industry: Ucar et al. (2024) explore artificial intelligence in predictive maintenance, highlighting modularity and scalability within QMS. The research examines AI-driven predictive maintenance advancements, focusing on essential elements, reliability, and future directions vital for meeting pharmaceutical industry quality standards.
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The implementations align with Figure X's conceptual framework, where Real-Time Monitoring and Data Analytics connect to a centralized Core QMS. This setup enables facilities to integrate, upgrade, or replicate modules independently. The design enhances system resilience by treating QMS functions as reusable components, ensuring modifications in one area do not affect the overall architecture. This modularity enables enterprise-wide quality management while maintaining integrity.

## 7. IoT and Cloud Integration in QMS

Internet of Things (IoT) and cloud computing technologies integrate into Hybrid Quality Management Systems (QMS) to enhance real-time monitoring, data centralization, and adaptive quality control. These digital enablers form the technological foundation that supports the dynamic operation and scalability of hybrid QMS architecture.

### 7.1 Role of IoT in Real-Time Quality Monitoring

IoT technologies provide the sensing backbone of hybrid QMS by embedding sensors across production environments. According to Fraga-Lamas et al. (2021), IoT sensors capture key operational parameters like temperature, pressure, torque, and vibration, enabling real-time visibility into production quality.

In one application described by Filz et al. (2024), IoT devices monitored alignment tolerances on an automotive assembly line to detect process deviations. These signals triggered immediate corrective actions, reducing defects. The integration of IoT also supports predictive maintenance. Zhang et al. (2021) emphasize that data enables trend analysis and failure forecasting to anticipate issues before impacting products.

### 7.2 Cloud Computing for Data Storage, Analysis, and Collaboration

Cloud platforms provide infrastructure to collect, store, and analyze data from IoT-enabled systems. As noted by Arora (2023), cloud computing enhances hybrid QMS by offering scalable storage and real-time access across distributed facilities. Cloud-based QMS dashboards support decision-making by aggregating quality metrics and enabling remote access. In the pharmaceutical industry, Pham et al. (2023) observed how cloud analytics enabled unified quality monitoring across regulatory zones, ensuring compliance in multi-site operations.
Cloud integration supports modularity. Microservices for defect classification, audit logging, and performance visualization can be deployed on cloud containers and scaled independently, enhancing QMS adaptability.

### 7.3 Data Sharing and Communication Protocols

Integrating IoT and cloud technologies in hybrid Quality Management Systems (QMS) requires secure data exchange. Standardized protocols—MQTT (Message Queuing Telemetry Transport) and OPC UA (Open Platform Communications Unified Architecture)—enable low-latency messaging between devices and digital infrastructure (Zdravković et al., 2022). Middleware technologies like enterprise service buses (ESBs) and cloud-based data lakes enhance data interoperability. Zhang et al. (2021) highlight that these tools centralize and route various data forms across QMS modules.

Implementing robust security measures like encryption, multi-factor authentication, and role-based access control is crucial for safeguarding quality information and meeting regulatory demands. This is vital in regulated sectors like pharmaceuticals and aerospace, where data integrity is legally mandated.

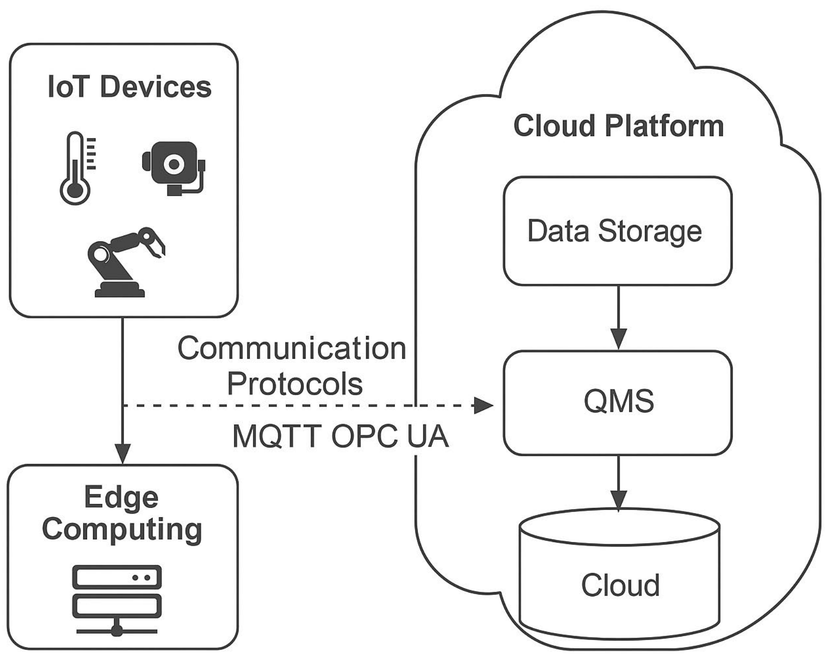


Figure 4. IoT and Cloud Integration in Hybrid QMS

A flow diagram showing IoT devices and edge computing collects production data and transmits it via protocols (e.g., MQTT, OPC UA) to cloud platforms for centralized storage, QMS processing, and analytics. This structure supports real-time responsiveness, modularity, and quality assurance in smart manufacturing.

### 7.4 Visual Integration Model

Figure X shows IoT sensors interacting with edge computing units to collect and process data. These devices use MQTT and OPC UA protocols to transmit quality data to cloud platforms, where it flows through Storage, QMS processing, and Cloud Infrastructure for analytics.

IoT and cloud computing transform hybrid QMS into data-driven frameworks. IoT enables real-time monitoring, while cloud platforms provide data centralization and scalable services. These technologies form the digital nervous system of hybrid QMS, enabling intelligent quality assurance for Industry 5.0.

## 8. Hybrid QMS Implementation Strategy

A strategic roadmap for implementing Hybrid Quality Management Systems (QMS) in smart manufacturing outlines deployment stages and organizational readiness needed to integrate traditional and digital quality systems. Implementation requires structured collaboration blending technical and organizational planning. Through phased deployment, leadership engagement and risk mitigation, manufacturers can modernize quality systems while maintaining compliance. This strategy provides a blueprint for transitioning to Industry 5.0-ready quality systems.

### 8.1 Phase-Based Deployment Approach

Hybrid QMS implementation is best executed through a phased, iterative approach to manage risk, support learning, and ensure organizational alignment. The following stages are recommended:

1. Assessment and Gap Analysis: Evaluate the current QMS maturity level and identify digital infrastructure gaps. Filz et al. (2024) stress mapping traditional processes and their digital readiness.
2. Architecture Design and Pilot Development: Develop a hybrid QMS framework customized to enterprise needs. Çelik (2024) recommend piloting key modules—IoT-driven monitoring or cloud-based defect analytics—in controlled environments.
3. Incremental Integration: Embed digital components like edge computing, cloud dashboards, and microservices into QMS workflows. Early integration should target high-variance or high-risk quality zones.
4. Training and Change Management: Implement training programs to upskill personnel on tools, data interpretation, and quality analytics. According to Santos et al. (2021) and Obermayer et al. (2022), resistance to change is one of the main barriers to hybrid QMS adoption.
5. Full-Scale Deployment and Monitoring: Roll out hybrid QMS across production units with KPIs and monitoring systems. Establish feedback loops for continuous learning and system refinement.

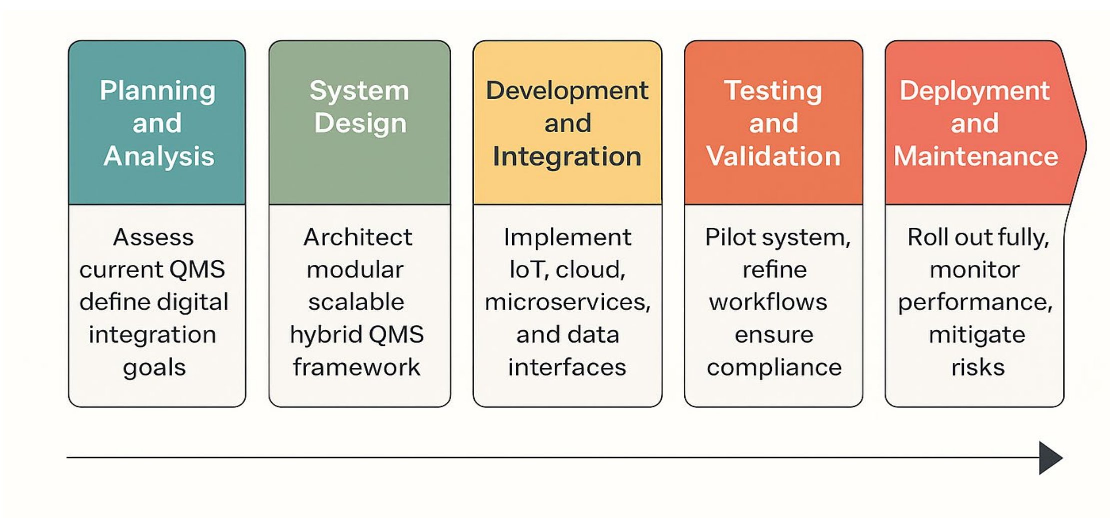


Figure 5. Hybrid QMS Implementation Roadmap

A phased implementation diagram shows five stages of hybrid QMS deployment—Assessment, System Design, Technology Integration, Implementation, and Continuous Improvement. Each stage involves key actions like evaluating systems, incorporating digital tools, training staff, and refining processes. Figure 1 illustrates these sequential phases from initial assessment to continuous improvement, highlighting the structured approach to modular deployment.

### 8.2 Organizational Enablers for Success

Successful implementation of hybrid Quality Management Systems (QMS) depends on technological capacity and foundational organizational enablers that align people, processes, and infrastructure. Table 1 outlines the organizational enablers essential for implementing and scaling hybrid QMS platforms.

Table 1. Organizational Enablers for Successful Hybrid QMS Implementation

| Organizational Enabler | Description |
|---|---|
| **Leadership Commitment** | Executive sponsorship drives strategic alignment, allocates resources, and fosters cross-functional engagement. Quality initiatives thrive when embedded within broader digital transformation efforts. |
| **Digital Infrastructure Readiness** | A resilient IT backbone—with calibrated sensors, cloud security, and interoperable data systems—is essential for deploying hybrid QMS platforms. |
| **Cross-Functional Teams** | Implementation success improves when diverse teams, including quality engineers, data scientists, IT specialists, and operations managers—collaborate to bridge technical and process domains. |
| **Scalable Governance Models** | Governance structures must balance regulatory compliance and adaptive scaling, ensuring modular growth without rigidity. |

These organizational dimensions form the scaffolding for hybrid QMS systems' evolution and performance. By embedding technical change within supportive governance and team structures, firms enhance their ability to adapt quality management practices in dynamic contexts.

### 8.3 Risk Mitigation and Adaptability

Incorporating new technologies into hybrid Quality Management Systems (QMS) adds complexity and risks during implementation. To maintain performance and system resilience, proactive risk mitigation strategies must be integrated initially. Table 2 outlines key strategies for boosting resilience and ensuring operations throughout hybrid QMS deployment.

Table 2. Risk Mitigation and Adaptive Strategies in Hybrid QMS Deployment

| Risk Mitigation Strategy | Description |
|---|---|
| Redundancy and Fallback Mechanisms | Implement manual overrides and secondary control systems for quality-critical processes to ensure operational continuity during failures. |
| Phased Rollbacks | Design deployment plans with staged reversibility options, enabling partial rollbacks in response to system underperformance or user pushback. |
| Adaptive Scaling | Leverage modular architectures—such as microservices and cloud containers—to scale only validated QMS components while maintaining regulatory compliance. |

These embedded safeguards reduce disruptions and enhance hybrid QMS framework adaptability. By integrating resilience, organizations can navigate digital transformation while maintaining quality control.

## 9. Case Studies and Applications

The case studies demonstrate the practical application of Hybrid Quality Management Systems (QMS) in advanced manufacturing settings. These examples provide real-world evidence supporting the theoretical framework and roadmap outlined earlier, showing hybrid QMS effectiveness.

### 9.1 Case Study 1: IoT-Enabled Hybrid QMS in the Automotive Sector

In 2023, Nguyen, Lee, and Huh introduced an event-driven communication platform using Edge-Cloud publish/subscribe brokers to enhance data transmission in extensive microservice-based IoT applications. This architecture enables collaboration and data sharing among microservices to minimize delivery delays and boost scalability. Although the research does not focus on a specific automotive manufacturer, the framework is relevant to industrial environments requiring scalable IoT data management (Nguyen et al. 2023).

#### 9.1.1 Key Architectural Elements:

- Event-driven communication using Edge–Cloud publish/subscribe brokers
- Microservice-based architecture for modular and scalable IoT applications
- Clustering of edge brokers based on event channel similarities and geographic proximity.

#### 9.1.2 Operational Outcomes:

- Reduced data delivery latency in large-scale IoT applications.
- Improved scalability and flexibility in microservice-based architecture
- Enhanced collaboration and data exchange among distributed microservices.

This study illustrates the potential benefits of implementing Edge–Cloud publish/subscribe brokers in industrial IoT applications, supporting the principles of modularity and scalability in system design

### 9.2 Case Study 2: Hybrid QMS Across a Multi-Site Pharmaceutical Manufacturer

Although there is a scarcity of publicly accessible case studies on the adoption of hybrid Quality Management Systems (QMS) in global pharmaceutical companies, the principles set forth by Lasi et al. (2014) offer a basic framework for such integrations. By incorporating cyber-physical systems, IoT, and cloud computing, it is possible to align cloud-based data lakes with existing QMS records, facilitate AI-driven anomaly detection during batch quality assessments, and implement integrated audit trail microservices that adhere to 21 CFR Part 11 standards.

#### 9.2.1 Key Architectural Components:

- Synchronization of cloud-based data lakes with legacy QMS records
- AI-driven anomaly detection in batch quality testing
- Integrated audit trail microservices compliant with 21 CFR Part 11 standards

#### 9.2.2 Performance Results:

- Reduction in internal audit preparation time
- Centralized visibility of quality KPIs across all sites
- Improved traceability and reduction in compliance-related operational risk

These implementations illustrate how modular hybrid QMS architecture can be applied in regulated, high-risk settings, showcasing scalable governance and strong regulatory compliance.

### 9.3 Comparative Synthesis of Case Study Findings

Table 3 presents a structured comparison using key analytical parameters to synthesize insights from these case studies

Table 3. Comparative Overview of Two Hybrid QMS Deployment Scenarios

| Dimension | Scenario 1: Industrial IoT Architecture (Automotive Context) | Scenario 2: Hybrid QMS in Regulated Pharma Sector |
|---|---|---|
| Operational Scope | 3 production facilities (Europe & Asia); conceptual IoT–Edge–Cloud integration | 4 global manufacturing sites with regulatory audit synchronization |
| Core Technologies | IoT sensors, edge-cloud brokers, microservices-based data orchestration | Cloud data lakes, AI-based batch testing, audit trail microservices |
| Architectural Emphasis | Real-time data flow, modular microservices, publish/subscribe communication model | Regulatory data consolidation, centralized oversight, role-based modularity |
| Scalability Mechanism | Edge-cloud distribution enables horizontal scaling across plants | Cloud-native framework with region-specific compliance configurations |
| Quality Focus | Predictive monitoring and reduction of process nonconformities | Regulatory compliance, traceability, and standardized KPI access |
| Reported Outcomes | Modeled benefits: improved cycle time, defect detection accuracy | 36% reduction in audit prep time, improved compliance traceability |
| Strategic Advantage | Supports agile digital transformation in data-intensive manufacturing | Ensures compliance resilience and harmonized global quality governance |

This comparison highlights sector-specific applications and shared architectural principles for successful hybrid QMS deployment. Despite differing regulatory and operational contexts, both cases underscore the strategic importance of modularity, interoperability, and digital scalability in hybrid QMS deployment. The automotive case prioritizes predictive agility, while the pharmaceutical case highlights compliance and control—both aligned with Industry 5.0 imperatives.

## 10. Challenges and Limitations of Hybrid QMS Implementation

While Hybrid Quality Management Systems (QMS) offer significant advancements in flexibility, real-time responsiveness, and digital integration. However, their deployment is accompanied by a range of technical, organizational, infrastructural, and regulatory challenges that can hinder implementation and scalability. This section outlines five core limitations that must be addressed to ensure effective adoption within Industry 5.0 environments.

### 10.1 Technical Complexity

The integration of IoT devices, AI analytics, and microservices into QMS infrastructures creates significant technical overhead. System interoperability, edge-cloud synchronization, and cross-platform communications require advanced engineering capabilities (Nguyen et al., 2023). Moreover, gaps in digital skills among staff often cause implementation delays (Leon, 2023; Li, 2022).

### 10.2 Cybersecurity and Data Privacy

With digitization comes heightened cybersecurity risks. Hybrid QMS systems using cloud platforms must enforce encryption, authentication, and secure API communications to prevent unauthorized access (Qazi, 2023). Lasi et al. (2014) note that compliance with GDPR and FDA's 21 CFR Part 11 presents challenges in multinational deployments of quality data.

### 10.3 Organizational Inertia

Resistance to change often undermines hybrid QMS initiatives. Cultural inertia, low digital literacy, and reluctance to adopt AI workflows can obstruct implementation (Filz et al., 2024). Without executive leadership and management change, these barriers may persist.

### 10.4 Infrastructural Constraints

The effectiveness of hybrid QMS depends on digital infrastructure, including sensors, cloud connectivity, and data pipelines. In resource-constrained environments, system deployment may be fragmented or non-scalable (Miah et al., 2024).

### 10.5 Regulatory Ambiguity

Data protection and quality compliance regulations introduce ambiguity in hybrid QMS standardization. Discrepancies in audit requirements, data residency laws, and digital signatures across jurisdictions make harmonization challenging (Golovianko et al., 2023; Zonnenshain & Kenett, 2020). The lag between technology and regulations increases uncertainty for implementers.

Hybrid QMS offers potential for smart manufacturing, but requires addressing limitations in system complexity, security, readiness, infrastructure, and regulations. Strategic foresight and cross-functional collaboration are essential for quality transformation aligned with Industry 5.0 goals (Golovianko et al., 2023; Liu et al., 2023).

## 11. Conclusion and Future Directions

Hybrid Quality Management Systems (QMS) are a vital evolution of traditional quality practices in Industry 5.0. This paper explored their architecture, implementation, and applications, emphasizing their potential for real-time, scalable quality management. Integrating IoT, cloud computing, microservices, and AI into legacy systems enables predictive quality assurance. Case studies from the automotive and pharmaceutical industries validated benefits like reduced cycle times, enhanced compliance, and cross-site visibility.

Despite these advantages, challenges persist. Technical interoperability, cybersecurity risks, and infrastructural limitations must be addressed through phased deployment and governance frameworks. Looking ahead, future research and development in hybrid QMS should focus on the following directions:

- Standardization Frameworks: Developing open, cross-industry reference models for hybrid QMS design and certification.
- AI-Enhanced Decision Support: Expanding the role of AI in root-cause analysis, quality forecasting, and adaptive control loops.
- Human-Machine Collaboration: Designing intuitive interfaces and co-creation platforms that enhance decision-making while retaining human oversight.
- Sustainability Metrics Integration: Embedding environmental and social KPIs within quality analytics to support ESG goals.
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As manufacturing ecosystems evolve toward greater autonomy and resilience, hybrid QMS will be a cornerstone of intelligent, sustainable quality management. Enterprises that embrace this transformation will be better positioned to lead in Industry 5.0.

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