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| RESEARCH ARTICLE

A Survey of Next-Generation Electronic Quality Management Systems for Global Regulated Enterprises

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| ABSTRACT

Next-generation Electronic Quality Management Systems (eQMS) represent the evolution of traditional paper-based quality systems into intelligent, cloud-based, and compliance-driven digital ecosystems. This study examines the organizational architecture, regulatory alignment, enabling technologies, and implementation challenges associated with next-generation eQMS in regulated industries such as pharmaceuticals and advanced manufacturing. Modern eQMS platforms integrate core quality modules including document control, CAPA, audit management, training, and change control into centralized and automated systems that enhance traceability, data integrity, and operational efficiency. The paper further evaluates compliance with global regulatory frameworks, including ICH E6(R2/R3), USFDA 21 CFR Part 11, EMA Annex 11, and PIC/S guidelines, with a focus on inspection readiness and lifecycle-based validation. Emerging technologies such as artificial intelligence, machine learning, cloud computing, blockchain, digital twins, and the Internet of Things are enabling predictive, real-time, and proactive quality management. Despite these advancements, implementation remains challenging due to legacy system integration, data complexity, resource constraints, and organizational resistance to digital transformation.

| KEYWORDS

Next-Generation eQMS, Regulatory Compliance, Digital Quality Management, Artificial Intelligence, Cloud Computing, Industry 4.0

| ARTICLE INFORMATION

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1. Introduction

Organizations invest significant resources in developing structured mechanisms to ensure and continuously improve the quality of processes, products, and services (Limón-Romero et al. 2024). A Quality Management System (QMS) is a strategic organizational framework that offers an organized pattern of ensuring continuous quality, operational efficiency and compliance with customer and regulatory requirements (Syed 2024). QMS implementation facilitates sustainable development, customer satisfaction, workforce engagement, and competitiveness in the integrated supply chains through standardization of the activities, control of documentation, and the performance monitoring.

Conventionally, QMS systems were heavily based on manual records, paper records, and disjointed control systems. Although they were standardized and in compliance, such systems were generally linked to inefficiencies, ineffective traceability, slow decision-making as well as the risk of human error (Antipov, Kuznetsova, and Aytasova 2020; Katangoori 2026). With the ever-changing digital world and the sophistication of regulatory systems, the traditional QMS practices are no longer sufficient to satisfy the requirements of instant monitoring, cross-border collaboration, and quality evaluation based on data. Quality management practices are fundamentally evolving through digitalization. The use of intelligent and automated systems and AI-based platforms slowly replaces the analog control system where decisions were made primarily by humans (Bacoup et al. 2018). Digital technologies enhance external competitiveness by enhancing productivity and scalability of operations and internal competitiveness by enabling real-time tracking, optimization of processes and timely mitigation of risks (Seetharaman 2022). In

highly regulated industries, such as pharmaceuticals, medical devices, aerospace, food processing and advanced manufacturing, digitalization is synonymous with compliance readiness, operational resilience and strategic growth.

To address these evolving requirements, Next-Generation Electronic Quality Management Systems (eQMS) have emerged (Bashan and Kordova 2022). In contrast to traditional systems, eQMS platforms are cloud-based and designed to automate quality processes, centralize documentation, guarantee the data integrity and real-time cooperation with geographically distributed locations (Kulkarni and Vemuri 2015). The peculiarities of this type of systems are that they are designed using the latest technology, including artificial intelligence, analytics, API-based interoperability, and secure audit trails, to comply with regulatory standards of compliance and operational excellence in international environments.

1.1 Structure of the paper

The remainder of the paper follows this structure. Section II describes the design and the basic components of the Next-Generation eQMS. Section III explains compliance systems worldwide that influence the implementation of eQMS. Section IV discusses enabling technologies and implementation issues. The literature review summary is presented in Section V, and the study concludes with Section VI, which presents the main findings and suggestions for further research.

2. Architecture of Next-Generation eQMS

Next-Generation eQMS are web-based electronic platforms that automate and centralize quality processes, including document control, CAPA, and audit management. They make it more compliant, more real-time, and more operationally efficient than a traditional paper-based QMS.

2.1 Electronic Quality Management Systems (eQMS)

An eQMS is a digital platform that consolidates, automates, and streamlines an organization's quality management processes (N. Prajapati 2025). Some of the elements included in the eQMS are document control, change management, training management, risk management, audit management, and Corrective and Preventive Actions (CAPA) (Narang and Kolla 2025; Pockle et al. 2023). A more contemporary and simplified method for managing quality processes is provided by an electronic quality management system (eQMS).

A quality management system generally includes four elements, as shown in Figure 1:

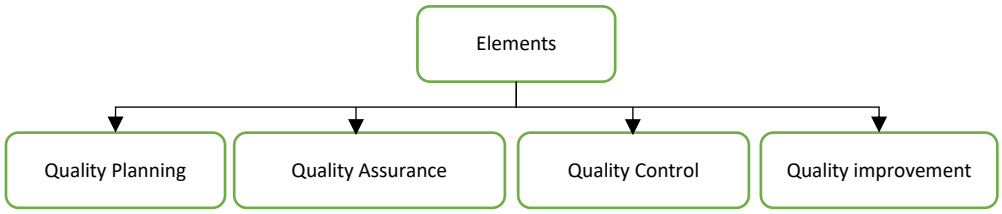

Figure 1: Core Components of a Quality Management System

- **Quality planning :** Quality planning is the process of putting different rules into the industrial processes and making a list of steps to follow to reach certain goals.
- **Quality assurance :** The term "quality assurance" is often used to describe a set of procedures designed to guarantee a product meets specified standards.
- **Quality control :** The goal of quality control is to ensure that all processes, procedures, and products are up to par by checking, managing, and correcting them as needed.
- **Quality improvement :** Accurately evaluating performance and then implementing systematic, methodical, and precise changes to enhance it constitutes quality improvement.

2.2 Next-Generation eQMS architecture

A Next-Generation Electronic Quality Management System (eQMS) is a multi-layered cyber-physical information system that is cloud-based and designed to enable enterprise-wide quality governance by tightly integrating application services, interoperable data exchange mechanisms and process automation through compliance (Gottipati and Pujari 2025). According to Fig. 2, the proposed platform has a hierarchical, multi-layered structure that isolates presentation, integration and orchestration, application services, data management and infrastructure issue. This layered design improves scalability, fault tolerance, interoperability and regulatory traceability and allows system components to be evolved independently.

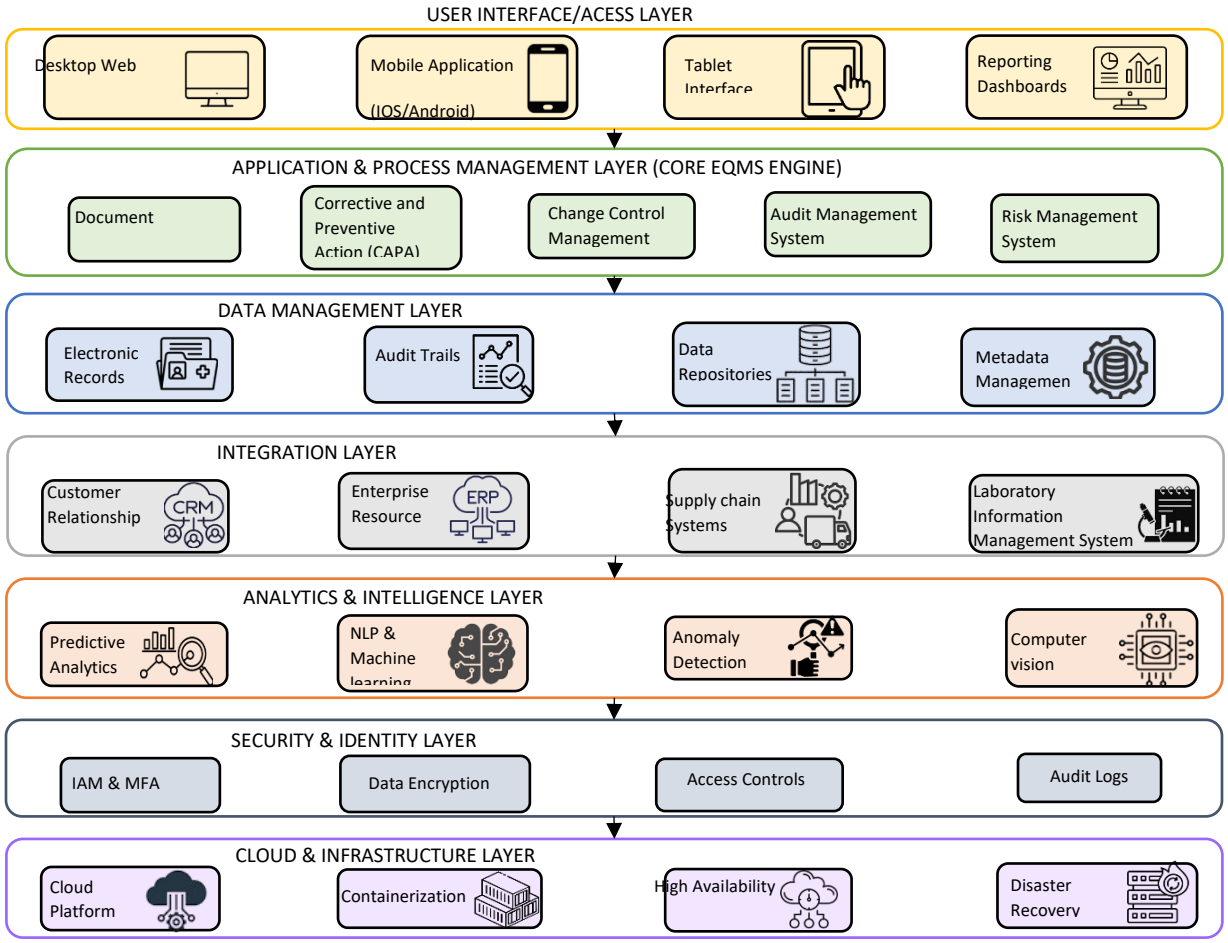

Figure 2: Layered Architecture of Next-Generation eQMS

2.2.1 User Interface / Access Layer

This layer serves as the primary interface through which users interact with the system and users interact with the eQMS through web and mobile interfaces (John Wesly Sajja 2024). It offers a unified access control environment, which is a combination of authentication systems including Single Sign-On (SSO) and role-based access control. The architecture is based on the constant communication with the services in the background, which makes it possible to visualize the data in real-time, have the responsive dashboards, and navigate between the system components easily. It provides a secure way of dealing with sessions yet makes sure to be synchronized with the underlying processes and system state.

2.2.2 Application Layer

The core functional modules of the electronic Quality Management System (eQMS) are found in this layer and go directly to support the user operations and business activities. It also consists of document management, CAPA, change control, audit management, complaint handling, and risk management. These modules in the architecture are closely interlinked, allowing the flow of data continuously and the coordination of quality processes. The layer applies business rules, provides adherence to regulatory standards, and keeps traceable records of all quality related activities.

2.2.3 Data Management Layer

This layer handles storing and organizing all the system information such as transactional records, documents and integrated enterprise data. It helps in storage of structured and unstructured information, which is consistent and accessible throughout the system. This layer ensures continuous data availability to upper layers to facilitate the smooth retrieval, updates, and synchronization of the data. Mechanisms like backup, replication and disaster recovery are included to ensure data integrity, reliability and operational continuity.

2.2.4 Integration and Communication Layer

This layer interrelates the eQMS with external enterprise systems, including the ERP, CRM, and LIMS, through the standardized interfaces and APIs (Macha 2022). It allows the free flow of communication, real-time data sharing, and protocol conversion between systems. The architecture focuses on data flow in both directions to ensure synchronisation, message routing and interoperability, whilst abstracting underlying system complexities and enabling traceability across organisational boundaries.

2.2.5 Analytics & Intelligence Layer

This layer transforms system wide data into significant insights using sophisticated analysis skills. It incorporates business intelligence, AI and ML to digest real-time and historical information (Tambare et al. 2021; Vaidehi Shah 2022). The architecture integrates analytics into operational processes, enabling predictive analytics, anomaly detection, trend analysis, and risk assessment. It allows quality management that is proactive and well-informed throughout the organization.

2.2.6 Security and Identity Layer

This layer can prevent the attacks of the system resources, data, and user identities at all the architecture layers. It consists of identity management, access control, encryption and monitoring to prevent unauthorized access and possible threats. The architecture incorporates built-in security controls, ensuring compliance with regulatory requirements without compromising data confidentiality, integrity, or availability.

2.2.7 Cloud and Infrastructure Layer

This base layer is the foundation that delivers the computing, networking and storage facilities necessary to support the whole eQMS architecture. It consists of cloud or hybrid environments of deployment, virtualization, and containerization, as well as network security. The architecture guarantees a high level of availability, scalability, and optimization of the performance and allows the system to cater to the fluctuating workloads and provide reliable and secure performance.

General architecture is a vertically integrated and constantly connected eQMS-wide system where the layers are built around the layer above, and the data moves through vertically without disruption, processes are automated, and the entire system coordinates its activities. It provides end-to-end traceability, data integrity, regulatory compliance, real-time visibility, and proactive quality management in complex enterprise environments.

3. Next-Generation in eQMS for Regulatory Compliance in Global Enterprises

Next-generation eQMS is relevant for ensuring regulatory compliance among international businesses by incorporating digital quality processes aligned with international regulatory standards. Regulatory compliance refers to adherence to relevant regulations, standards, and specifications. Within the framework of Enterprise Content Management (ECM), compliance ensures that organizations handle their content in accordance with applicable legal and regulatory requirements, reducing risks and safeguarding confidential information. This section outlines the definition and applicability of regulatory compliance, identifies regulations that impact ECM, and explains how the regulatory environment is changing.

3.1 Understanding Regulatory Compliance

The eQMS implementation is subject to strict adherence to a set of international and local regulatory requirements:

3.1.1 USFDA 21 CFR Part 11

This rule was drafted by the United States Food and Drug Administration (FDA) to explain the situation under which digital records, and digital signatures may be taken as credible, official, and synonymous with paper records and handwritten signatures (Alharbi and Qureshi 2025). It entails powerful controls to ensure the authenticity, integrity and confidentiality of electronic data.

3.1.2 EMA Annex 11

EMA Annex 11, applies to all computer systems used in the Good Manufacturing Practice (GMP) activities within the European Union. It emphasizes that risks should be managed during the life cycle of a computerized system, including design and retirement.

3.1.3 ICH E6(R2/R3)

The International Council on Harmonization of technical requirements in pharmaceuticals used by humans is called the International Council on Good Clinical Practice (GCP). These rules are highly significant for data integrity and the use of computers in clinical research. Two core provisions of ICH E6(R2) are risk-based quality management and electronic system validation, both of which are used in clinical studies.

3.1.4 PIC/S PI 011-3 & PI 041-1

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) addresses issues related to computer systems and data security (Dok et al. 2025). PI 011-3 is a document that provides the specifications of computerized systems in GMP environments. It emphasizes the need to conduct a risk assessment to determine the extent of validation and ensure GxP compliance. PI 041-1 concerns Good Practices in Data Management and Integrity. It discusses concepts such as ALCOA+ and emphasizes the need for effective data control throughout the data lifecycle.

3.1.5 ANVISA (RDC 658, IN 134, Guide No. 33)

Computer System Validation (CSV) has become a legal aspect in the National Health Surveillance Agency (ANVISA) regulations in Brazil. The fundamental guidelines of GMP validation are provided in RDC 658. Normative Instruction (IN) 134 provides supplementary GMP requirements for computerised systems used in the manufacture of medicines and is compliant with PIC/S guidelines. It is based on the ISPE GAMP 5 model and categorises software and hardware to inform specific validation based on risk and complexity.

3.1.6 SAHPRA (MCC) Guidelines

The Good Manufacturing Practice (GMP) regulations are ensured by the South African Health Products Regulatory Authority (SAHPRA), formerly known as the Medicines Control Council (MCC). These regulations have certain requirements for electronic systems.

These regulatory frameworks collectively impose stringent requirements on data integrity, system validation, audit trails, and security controls. For global enterprises, the need to comply with multiple regulatory bodies introduces complexity in system design, requiring flexible, scalable, and configurable eQMS architectures.

3.2 The Role of Regulatory Compliance in ECM Strategies

Enterprise Content Management (ECM) plays a critical role in eQMS by governing document lifecycle, data integrity, and compliance workflows. Regulatory compliance is an important step in defining Enterprise Content Management (ECM) strategies. The compliance aspect of ECM practices has become necessary as organizations face stringent rules governing data management. This part examines the effects of regulatory compliance on the creation and management of content, storage and retrieval procedures and content disposal and archiving.

3.2.1 Impact on Content Creation and Management

Regulatory compliance requires a formal method for data classification and labelling that categorizes data by sensitivity levels and regulatory requirements. The significance of sound data classification includes:

- **Identification of Sensitive Data:** The laws such as GDPR and HIPAA require companies to establish and categorize the types of sensitive data, which comprises the protected health information (PHI) and personally identifiable information (PII). This identification assists in applying appropriate security measures.
- **Standardized Labelling Practices:** Their labelling would be a unified process that would facilitate the recognition of the same data in the organization. This may be the categorization of such information, which determines whether it is confidential or internal, and is applicable to employees.

3.2.2 Metadata Management

Regulatory compliance requires metadata management as it gives data meaning and structure, enhances reporting and governance. Key aspects include:

- **Comprehensive Metadata Documentation:** It is advisable that organizations uphold a clear metadata of any data which on the one hand, includes information on the source of any data, on the other hand, the owner of the data, rights of access and history of modification (Snehamruth 2024). This documentation is not elective towards conforming with regulations of transparency and accountability in data management.
- **Automated Metadata Capture:** The metadata capture tools are automated to ensure production of metadata that keeps on being updated as the content is produced and revised. This increases the accuracy of metadata as a compliance tool and minimizes the possibilities of human error.

3.2.3 Influence on Storage and Retrieval Processes

Regulatory compliance stipulates that organizations must have strict data retention policies that determine the duration of retention of various types of data. Key considerations include:

- **Legal and Regulatory Requirements:** The retention period of the different types of content is also controlled. SOX requires that some financial records should be kept within a period of 7 years and HIPAA has the same requirement that healthcare companies should maintain patient records at least 7 years.
- **Retention Schedules:** The retention schedules built on compliance are created in a manner that the material is retained for an appropriate duration and at the same time, when it is supposed to be removed (Rahman, Nahar, and Mim 2026). Such schedules help an organization avoid the risk of storing data longer than necessary, which increases the risk of data breaches.
- **Regular Audits and Reviews:** The organizations should also revise their data retention practices periodically to ensure that they are not breaking any rules. This is a proactive step, which would assist in detecting possible problems before non-compliance.

3.2.4 Access Controls and Security Measures

Access controls and security in Enterprise Content Management (ECM) strategies require regulatory compliance. Key elements include:

- **Role-Based Access Control (RBAC):** The RBAC mechanism can also be deployed to ensure that an authorized user can only gain access to personal data when a user is authorized. This is not something that can be accomplished with paramount importance, with the aim of complying to the stipulations whereby stringent access controls are required to prevent unauthorized parties to access sensitive information.
- **Audit Trails and Logging:** The compliance requires that the detailed audit trails must be utilized to record any access, and any kind of modification to the content (Garg 2020). This implies that such registries contain the names of the parties that have accessed what information and at what time, which is essential in proving compliance during the audits.

3.2.5 Effects on Content Disposal and Archiving

The need to use compliance-based schedules of retention has a direct effect in the way the organization is dealing with content disposal and archiving. Key considerations include:

- **Clear Disposal Policies:** Organizations are advised to establish clear rules regarding the way to dispose of useless materials. This entails the requirements regarding the physical disposal/destruction of documents and safe removal of electronic documents, as required by the regulations.
- **Automated Disposal Processes:** The possibility of a human error can be minimized by the implementation of automated methods to the safe disposal of the content based on the retention schedules. Using the assistance of automated programs, secure and compliant deletion of data is possible.

4. Enabling Technologies and Challenges in Next-Generation eQMS

The pharmaceutical industry has been traditionally underdeveloped digitally as compared to other key industries. It is quickly adopting digital transformation in its R&D processes, manufacturing and quality processes. This change is caused by the necessity to be more agile and efficient and the desire to manage complex operations in real time in a precise way. This change is having a large impact on electronic Quality Management Systems (eQMS).

4.1 Integration of Advanced Technologies within eQMS

4.1.1 Artificial Intelligence (AI) and Machine Learning (ML)

The use of AI and ML can help shift quality management from reactive to proactive, a significant transition that these technologies may enable (Palwe 2026). These technologies process big data collected by manufacturing machines and processes to identify potential failures or quality issues in advance. Other tasks automated by AI include document control workflows, enhancing auditing by detecting high-risk areas, and customizing training programs for each employee and area of knowledge deficiency (Lingam 2025). In addition to enhancing the quality of operations, AI is also revolutionizing the process of drug discovery by enhancing the process of molecular screening and design, significantly reducing the development timeline and reducing costs.

4.1.2 Internet of Things (IoT)

IoT sensors can be useful for monitoring critical parameters during pharmaceutical production. These include temperature, humidity, pressure and vibration (Aleem et al. 2024). The data stream continuously provides the right information at the right time about changes beyond predetermined limits. This enables rapid response and proactive quality management. Strict control of the environment and early detection of issues minimize product losses and ensure product quality.

4.1.3 Cloud Computing

Cloud-based eQMS is more flexible and scalable than any other. They provide storage systems that improve collaboration, quick accessibility of information and better data control to teams that are situated globally (N. K. Prajapati 2025; Sharma 2025). The model enables organizations to scale their QMSs without incurring massive infrastructure investments.

4.1.4 Blockchain

Distributed ledger technology can provide permanent records across the pharmaceutical supply chain, from the acquisition of raw materials to final product delivery, making it much easier to trace products and significantly reducing the risk of data tampering. Integrity and security of the data are ensured through recording and time-stamping every transaction. This is required to check the origin of products, detect counterfeiting and effectively recall products.

4.1.5 Digital Twins

Digital twins are simulations of physical processes, equipment or entire factories. These twins receive real-time sensor data from their physical counterparts. This data allows for simulation, monitoring, and improvement of drug production processes. This technology allows pharmaceutical companies to test new formulations, simulate process changes, and predict the performance of manufacturing equipment (Patel and Patel 2022). This strategy minimizes risks and expenses before making real-world changes.

4.2 Challenges in Implementing eQMS

Despite Next-Generation Electronic Quality Management Systems (eQMS) offering substantial advantages, their deployment is a resource-intensive and complicated process. The shift from traditional quality frameworks to smart, cloud-based systems entails complex issues across technical, regulatory, organizational, and operational fronts (Sajja and Kolli 2024).

4.2.1 Legacy System Modernization and Integration

Many organizations continue to operate heterogeneous legacy systems developed over long periods, including standalone databases, records, and proprietary software. These systems are not necessarily unified in their interface and cannot be used in real-time communication with modern platforms. They require significant system reconfiguration, middleware packages, and an ad hoc data connector to integrate with a Next-Generation eQMS. The lack of consistent data structures, technologies, and documented processes is worsening integration efforts. The inability to achieve a smooth integration may lead to non-completion of workflows, data redundancy, and reduced automation value, thus limiting the performance of the eQMS (Barot 2025; Kofi 2025).

4.2.2 Data Migration and Integrity Assurance

The migration of historical quality data from paper archives, spreadsheets and fragmented electronic systems to a central repository is a highly sensitive process. Organizations must make sure that every record is transferred correctly and never lost, modified or corrupted, and that metadata, timestamps and audit trails are maintained. The regulatory environment needs to be very compliant with the principles of data integrity; incomplete or untrustworthy migration can result in compliance risks and put decision-making under threat. Moreover, massive amounts of legacy data might also need cleansing, standardization, and validation, which can greatly add project complexity, time, and cost.

4.2.3 Regulatory Validation and Compliance Requirements

The Next-Generation eQMS solutions must be in accordance with rigid international rules of electronic records, digital signatures, and quality procedures. To prove compliance, it is necessary to perform extensive validation throughout the system lifecycle, including verification of installation, functional testing, performance evaluation, and recording of all activities. Any upgrade or change to the system might require partial revalidation of the existing workload in the long term. The need to meet the demands of regulatory authorities across jurisdictions only adds complexity, especially for multinational enterprises that must comply with multiple compliance systems.

4.2.4 Cybersecurity and Data Privacy Risks

Contemporary eQMS systems are generally cloud-based and linked to enterprise systems, suppliers, and remote consumers, thereby greatly increasing the attack surface for cyber threats (Gupta 2022). Sensitive quality records, intellectual property and regulatory documentation can be compromised by unauthorized access, ransomware attacks, insider threats and data breaches (Sirikonda 2026; Tissir, El Kafhali, and Aboutabit 2021). To ensure strong cybersecurity, advanced protective programs that include encryption, multi-factor authentication, secure access controls, 24-hour monitoring, and incident response strategies are required. Moreover, firms need to comply with the emerging and evolving data protection laws, and maintaining security controls may be a costly, continuous undertaking.

4.2.5 Organizational Resistance and Skill Gaps

Human factors play a critical role beyond technological implementation, and this is necessary to implement a Next-Generation eQMS. Employees who are used to a more traditional paper-based process may not easily embrace a transition to a digital process since they may find it cumbersome, more responsibility may be feared, or they may worry about their position. Furthermore, advanced skills in digital technologies, data management and compliance processes are required in advanced systems. Lack of appropriate training and change management can result in improper use of the system, reduced productivity and an inability to attain the anticipated benefits. Sustainable implementation should then require developing a digitally competent workforce and a culture conducive to transformation.

5. Literature Review

The literature review focuses on the digitalization of quality management systems, especially the evolution of eQMS, digitalization of cybersecurity, regulation standardization, and the evolution of TQM 4.0 according to the industry 4.0 technologies. But, as recent study as summarized in Table I explains, AI, big data, blockchain and smart manufacturing are changing compliance, resilience and predictive quality management in regulated industries.

Vyawhare (2025) discusses the transformation of the pharmaceutical industry by electronic Quality Management Systems (eQMS). This change is necessitated by the need to enhance the quality of products, operational efficiency, and compliance with regulations. It shows the core benefits of eQMS, such as automation and real time data. It also covers different emerging technologies that transform the quality standards, such as blockchain, the Internet of Things, cloud computing and AI. The article is dedicated to the complicated international regulatory environment. It has USFDA, EMA, ICH, WHO, PIC/S, MCC/SAHPRA and ANVISA guidelines on the integrity of data and verification of computerized systems.

Pujari and Gottipati (2025) explore the ways in which cybersecurity can become a part of the quality management system frameworks to guarantee compliance with the regulations, data integrity, and the quality of the products. This is the overall evaluation of the theoretical models, experimental case studies, industrial practices and regulatory requirements. Along with the measurement of technical tools like AI and blockchain, the article also reviews the current issues of implementation and suggests the course of future research. As it has been demonstrated, quality management systems (QMS) provide multiple advantages in the context of cybersecurity being established as a supporting layer, such as threat protection, resilience, and audit preparedness. Finally, the article states that in the future in order to develop a cyber-resilient QMS, cross-functional cooperation, revised regulatory frameworks and adaptive technologies must be present.

Wu *et al.* (2025) present data on the visible benefits of implementing an eQMS. Among the lessons learned in this experience, in practice, there was comprehensive staff training, gradual implementation strategies, and strict eQMS platform selection. Besides addressing implementation challenges commonly, the report gives certain recommendations on how to go about it. The best practices and lessons learned discussion related to this aspect can be of great value to other educational institutions that are contemplating the adoption of an eQMS. Finally, an eQMS can help academic CGT manufacturers to conduct business more effectively and stay in pace with the fast-changing discipline.

Bhikadiya (2024) analyses the formation, aspects, and development of QMS and highlights their importance in the current pharmaceutical sector. The revolution that globalization has brought to the pharmaceutical standards, innovation of the technological processes and innovations of the quality management strategies and all these are valuable lessons. There is also a detailed discussion of the issues surrounding personalized medicine as well as how the adaptive quality-control systems are changing business processes. To meet the constantly evolving needs of the industry, this analysis emphasizes the need for strong, flexible quality management systems, with an emphasis on patient safety, regulatory compliance and continuous development.

Kabir, Rana, and Debnath (2024) set a number of challenges, and they are justified by the sophistication of the global products, the complexity of supply networks and legal inflexibility. The high-tech therapeutics like personalized pharmaceuticals and biologics demand an extremely controlled environment, but globalization is a menace as it suffers failures in logistics and lacks uniformity in quality. Good anti-counterfeiting strategies are essential as the phenomenon of fake and low-quality pharmaceuticals is becoming more and more widespread, another burden to the supply chain. There is also the complexity of regional differences in regulations and the implementation of modern technologies, including continuous manufacturing. This demands resources and skills.

Van, Hieu, and Tucek (2023) developed a theoretical framework for TQM 4.0 by reviewing 203 publications from the Web of Science database. Offers 21 indicators for TQM 4.0 practices after thoroughly analyzing 20 key articles. The Pareto analysis was used to identify the thirteen most essential factors. This study delves further into TQM 4.0's five pillars: technical, social, smart organization, smart factory, and smart product. Using a bibliometric approach to analyze publication keywords, the study provides a

comprehensive understanding of TQM 4.0 and related hot topics. Digital transformation, sustainability, and quality culture are among the topics covered by TQM 4.0 research, according to the bibliometric analysis. Other topics covered include Industry 4.0 technologies such as big data, AI, and ML.

Table 1: Summary of Recent Studies on EMS for Global Regulated Enterprises

Authors (Year)	Study On	Approach	Key Findings	Challenges / Limitations	Future Work
Vyawhare (2025)	Transformation of the pharmaceutical industry through eQMS	Analytical review of regulatory frameworks and emerging digital technologies	eQMS enhances product quality, operational efficiency, regulatory compliance, automation, and real-time data access. Integration of AI, IoT, cloud computing, and blockchain is redefining quality standards.	Complex global regulatory landscape; strict data integrity and computerized system validation (CSV) requirements across agencies like USFDA, EMA, ICH, WHO, PIC/S, SAHPRA, and ANVISA.	Development of harmonized global compliance frameworks and advanced AI-driven validation mechanisms for regulatory alignment.
Pujari & Gottipati (2025)	Integration of cybersecurity into QMS frameworks	A thorough evaluation of relevant legislation, business standards, real-world examples, and theoretical frameworks	Cybersecurity as a foundational layer strengthens regulatory compliance, data integrity, audit readiness, and operational resilience. AI and blockchain enhance system security.	Implementation complexity, lack of updated regulatory guidelines, and cross-functional coordination gaps.	Creation of adaptive cyber-resilient QMS models and revision of regulatory frameworks to address evolving cyber threats.
Wu *et al.* (2025)	Practical adoption of eQMS in academic CGT manufacturing	Case-based implementation study with phased rollout and staff training strategies	eQMS adoption improves efficiency, documentation control, and compliance management. Careful platform selection and phased deployment are critical for success.	Resistance to change, training gaps and technical integration issues during the transition from legacy systems.	Development of standardized implementation frameworks and best-practice guidelines for academic and small-scale manufacturers.
Bhikadiya (2024)	Evolution and advancements in QMS in the pharmaceutical industry	Conceptual and analytical review of modern QMS frameworks	Fusion of cutting-edge tech, quality management based on risk, and transformation driven by globalization. Focus on ensuring patient safety and continuous improvement.	Challenges of personalized medicine, adaptive quality controls, and rapidly changing regulatory expectations.	Agile QMS frameworks tailored for personalized medicine and digital transformation ecosystems.
Kabir, Rana & Debnath (2024)	Challenges in modern pharmaceutical quality systems	Analytical review of global supply chains and regulatory complexities	Advanced therapies require precise environmental controls. Global supply chains increase risks of inconsistency, counterfeit drugs, and regulatory variations.	Resource constraints, logistical vulnerabilities, inconsistent global standards and anti-counterfeiting enforcement limitations.	Strengthening anti-counterfeiting technologies, harmonizing global standards, and integrating continuous manufacturing into QMS.
Nguyen, Nguyen & Tucek (2023)	TQM 4.0 theoretical framework development	Bibliometric review of 203 Web of Science articles; Pareto analysis	Discovered twenty-one TQM 4.0 indicators and five pillars: technological, social, smart organization, smart manufacturing, and smart product. Integrates AI, big data, and ML—the tools of Industry 4.0—with a focus on quality and sustainability.	Limited empirical validation; the conceptual framework requires real-world implementation studies.	Empirical testing of TQM 4.0 indicators and integration with Industry 4.0-enabled eQMS platforms.

6. Conclusion and Future Work

Next-Generation Electronic Quality Management Systems (eQMS) represent the next wave of quality governance in regulated industries, where fragmented manual controls are being eliminated and replaced with integrated, intelligent, cloud-enabled environments. By centralizing document control, CAPA, audit, change and training management, these systems enhance transparency, traceability and real-time decision-making. Data integrity and inspection preparedness in distributed enterprises

worldwide are ensured through compliance with international standards, including ICH guidelines, EMA guideline 11, and US FDA 21 CFR Part 11. By combining Artificial Intelligence, Internet of Things, cloud computing, blockchain, and digital twins, predictive quality management, round-the-clock monitoring, and active risk reduction will become possible. The paper summarizes global regulatory norms, provides a systematic overview of the technologies that enable Industry 4.0, and critiques implementation obstacles, including legacy integration, validation complexity, cyber risks, and organizational resistance. It also provides a conceptual framework for digital transformation and quality management with a compliance focus. Overall, next-generation eQMS delivers a strategic foundation for resilient, sustainable, and globally competitive quality ecosystems.

Future research needs to develop AI-autonomous compliance models, risk-autonomous validation models, and standard interoperability models. The solutions in this work, the extensions of the work, the explanation of AI as a source of regulatory trust, the cybersecurity-by-design architecture, the implementation of a digital twin at scale and the human-focused adoption models are the keys to creating adaptive, predictive and globally harmonized eQMS ecosystems.

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