Implementation of an Electronic Quality Management System (eQMS) to Enhance Document Control and Training Compliance in a Regulated Environment

Claudia C. Ramos Ahmad
Master in Manufacturing Competitiveness
Advisor: Dr. Rafael Nieves, PharmD.
Polytechnic University of Puerto Rico
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Abstract *— The implementation of an electronic Quality Management System (eQMS) marked a significant shift from a paper-based document control and training process at a regulated biopharmaceutical company. Aimed at enhancing operational efficiency, regulatory compliance, and data integrity, the initiative led to the successful migration of 67 controlled documents and the digitalization of 712 training activities—over 58% of which were completed within 15 working days post-Go-Live. The eQMS introduced automated workflows, electronic signatures, audit trails, and role-based access controls, aligning with FDA 21 CFR Part 11 and CGMP standards. As a result, training cycle times were reduced from five days to under one hour, and document approval timelines improved by 50%. Challenges such as license allocation and user adaptation were addressed through strategic planning and stakeholder engagement. The initiative showcases the transformative impact of digital platforms on quality management and establishes a scalable foundation for future organizational growth.*

Key Terms *— Compliance, Digital Platform, eQMS, Efficiency, Paper-Based, Traceability.*

PROBLEM STATEMENT

The current complication for the company working with a paper-based document control system is that there are limitations to efficiency, traceability, and compliance. This project will focus on the implementation and impact that transferring to an eQMS, a digital platform, has on the mentioned categories. Which will be observed in the various phases starting on June 2025 till September 2025. By transitioning to a digital based system, the company expects to improve in all areas that are currently lacking. The ultimate goal is to modernize compliance, significantly improve operational efficiency, and establish a scalable, secure digital environment for all document and training management.

RESEARCH DESCRIPTION

The transition from a paper-based to an electronic document control system requires a comprehensive understanding of both regulatory requirements and operational needs. The project focuses on investigating how the new system can improve compliance, efficiency, and accessibility. Research included evaluating current bottlenecks in document tracking, exploring best practices for system implementation, and defining SOP requirements that would be impacted by the transition. Additionally, the project considered training needs, since successful adoption depends on ensuring that all personnel, from Quality Assurance (QA) to operations staff, are proficient in using the new eQMS. The research will follow a structured implementation and validation approach, emphasizing regulatory alignment, user readiness, and system sustainability.

RESEARCH OBJECTIVE

The primary intention of this research is to successfully implement a new electronic Quality Management System (eQMS) for document control and training at the company's site, effectively replacing the current paper-based system. This transition is essential for addressing critical inefficiencies in document management and ensuring regulatory compliance.

To achieve this main goal, two primordial objectives have been identified to ensure the project's success. The first is to migrate 100% of all controlled documents from the Quality Assurance (QA) department to the digital platform. This will centralize all critical quality documents, ensuring version control and traceability. The second is to transition all training activities from the current paper-based format to the digital platform. This includes not only training personnel on the new system but also managing and tracking all employee training records digitally to ensure 100% compliance.

In addition to these primordial objectives, two secondary objectives will guide the implementation process. The first is to establish a digital workflow for the review, approval, and distribution of SOPs to streamline the document lifecycle and reduce processing times. The second is to implement a robust validation and testing protocol to ensure the digital system meets all regulatory requirements and operational needs before full-scale deployment. By prioritizing these key objectives, the project will ensure a smooth, compliant, and efficient transition to a modern digital system.

RESEARCH CONTRIBUTIONS

This project contributes to organizational growth by replacing an inefficient paper-based system with a fully digital, compliant, and auditable document control process. The new digital system will ensure version control and traceability of all documents; provide structured training modules to ensure personnel competence; enhance audit readiness by enabling instant document retrieval, and improve efficiency and compliance, reducing risks of human error.

In the long term, the successful implementation of the eQMS will serve as a foundation for expanding digital quality management solutions across the organization, while also providing employees with skills aligned with modern compliance systems.

LITERATURE REVIEW

This section explores the transition from paper-based to digital document control systems, The company's transition to a new electronic Quality Management System (eQMS) is driven by the significant limitations of the current paper-based document control system, which hampers efficiency, traceability, and compliance. Manual processes introduce high risks of human error, slow document approval, and difficulty in maintaining version control. Digital platforms directly resolve these issues by offering centralized repositories, automated workflows, and real-time documentation access. Specifically, a comprehensive review by Basir et al. found that digital systems significantly improve data accuracy, accessibility, and collaboration, directly supporting the strategic decision to adopt the eQMS for enhanced operational efficiency and regulatory readiness [1].

A foundational aspect of this transition is ensuring Data Integrity and Regulatory Compliance, as defined by the FDA as the completeness, consistency, and accuracy of data throughout its lifecycle. The FDA's Guidance for Industry on Data Integrity and Compliance with CGMP outlines critical expectations for electronic systems, including unique user credentials, audit trails, and electronic signatures [2]. The eQMS directly addresses these requirements with automated audit trails that track every interaction, role-based access control to prevent unauthorized changes, and electronic signature functionality compliant with 21 CFR Part 11. This robust functionality positions the new system to meet and exceed regulatory expectations, strengthening data integrity across all quality documentation.

Successful system adoption relies heavily on structured training and changes management. The new eQMS is a validated system that integrates document control, training management, and quality processes, making it critical that personnel are trained in the latest procedures. Research by Day et al. highlights that leadership-driven training programs improve engagement and performance

during system transitions [3]. Furthermore, Phillips & Klein emphasize that comprehensive change management, including clear communication and stakeholder engagement, is essential for training success [4]. By incorporating both in-person and system-based training with a robust post-go-live support strategy, the project is aligned with best practices to ensure full user adoption and maximize the eQMS's benefits, which include enhanced compliance and streamlined quality management processes.

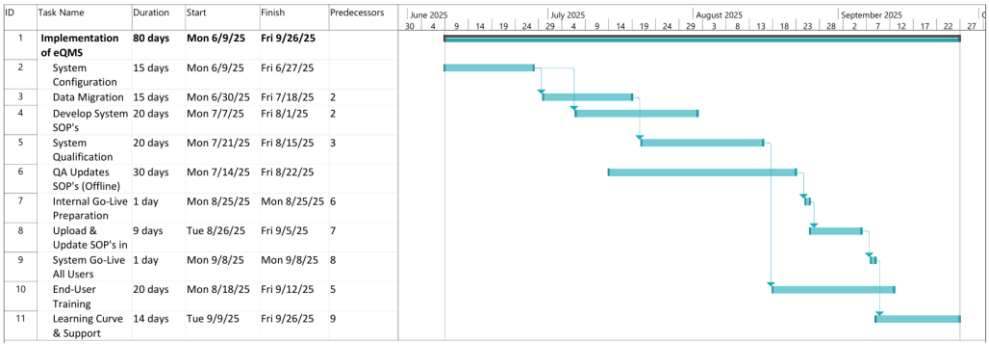
METHODOLOGY

The implementation of the electronic Quality Management System (eQMS) for document control and training will follow a structured, phased methodology to integrate quality assurance principles, validation protocols, and change management strategies. The goal is to ensure regulatory compliance, user adoption, and long-term sustainability. The entire project is precisely aligned with the milestones presented in the project timeline, which is visually detailed in Figure 1: Project Gantt Chart.

The methodology is broken down into three key stages: Initial Setup and Content Preparation, System Validation and Training, and Final Deployment and Support.

The initial stage comprises the first three phases, focusing on building the system's structure and preparing the necessary content. Phase 1: System Configuration (June 9 – June 27, 2025) establishes company-specific requirements, including defining document hierarchies (policies, SOPs), configuring role-based access controls, enabling audit trails, and establishing the essential training matrix framework. Phase 2: Data Migration and Document Setup (June 30 – July 18, 2025) involves the physical digitization and upload of existing SOPs and controlled documents, followed by validation against original records to establish version control. Running in parallel, Phase 3: QA Offline SOP Updates and Creations (July 14 – August 22, 2025) ensures the Quality Assurance (QA) team revises outdated procedures and creates new SOPs (e.g., for system use) offline to meet current CGMP and regulatory expectations before they are uploaded for final approval.

The second stage is dedicated to ensuring compliance and preparing the end-users. Phase 4: Qualification of eQMS (July 21 – August 15, 2025) is a critical compliance checkpoint, involving the execution of User Acceptance Testing (UAT) and verification of electronic signature functionality to validate adherence to FDA 21 CFR Part 11 and internal standards. The main delivery is a comprehensive qualification package. Following this, Phase 5: End-User Training (August 18 – September 12, 2025) is conducted by the QA team, providing in-person workshops for power users and system-based training modules for all employees, using the activated training matrix to auto-assign role-specific SOP training tasks.



ID	Task Name	Duration	Start	Finish	Predecessors
1	**Implementation of eQMS**	**80 days**	**Mon 6/9/25**	**Fri 9/26/25**	
2	System Configuration	15 days	Mon 6/9/25	Fri 6/27/25	
3	Data Migration	15 days	Mon 6/30/25	Fri 7/18/25	2
4	Develop System SOP's	20 days	Mon 7/7/25	Fri 8/1/25	2
5	System Qualification	20 days	Mon 7/21/25	Fri 8/15/25	3
6	QA Updates SOP's (Offline)	30 days	Mon 7/14/25	Fri 8/22/25	
7	Internal Go-Live Preparation	1 day	Mon 8/25/25	Mon 8/25/25	6
8	Upload & Update SOP's in	9 days	Tue 8/26/25	Fri 9/5/25	7
9	System Go-Live All Users	1 day	Mon 9/8/25	Mon 9/8/25	8
10	End-User Training	20 days	Mon 8/18/25	Fri 9/12/25	5
11	Learning Curve & Support	14 days	Tue 9/9/25	Fri 9/26/25	9

Figure 1
Project Gantt Chart

With the validation process completed, the final steps ensure the system is ready for company-wide use. Phase 6: QA Final SOP Upload and Review (August 25 – September 5, 2025) occurs right before Go-Live, during which QA finalizes the upload of all revised SOPs, closes any open review cycles, and ensures all SOPs are correctly linked to their required training modules. The key deliverable is a fully updated and prepared SOP library.

The project culminates with Phase 7: System Go-Live on September 8, 2025. This official company-wide launch activates all SOPs and workflows, enables real-time reporting dashboards, and transitions the entire organization to digital operations for document and training management. The successful deployment is confirmed by Go-Live dashboard reports that summarize overall system readiness and deployment success.

The methodology concludes with Phase 8: Post-Go-Live Support (September 9 – September 26, 2025). This dedicated period provides essential user support to ensure smooth adoption and monitors training completion and document workflows to confirm system effectiveness. The final step is a post-Go-Live performance report, supported by compliance dashboards summarizing all training and document activity, thus creating a comprehensive framework for compliance, efficiency, and scalability, as outlined in the project's summary.

Results and Discussion

In this section of the project, we successfully completed the implementation of the electronic Quality Management System (eQMS), achieving the primary objective of transitioning from a manual, paper-based system to a fully digital quality platform. This shift aligns with industry findings, demonstrating reduced inefficiencies and enhanced regulatory readiness. A critical early step was System Qualification, which validated the platform's configuration against regulatory requirements (like FDA 21 CFR Part 11) and internal standards. This phase confirmed the successful migration and validation of all 67 controlled documents. The Audit Trail and version control features, essential for data integrity and traceability, were activated and verified, a significant improvement over the manual process.

A key finding during configuration was an unexpected license discrepancy: 34 of 47 employees required a full license for key functions (creation, review, and approval), with only 13 needing a basic license, as shown in Figure 2.

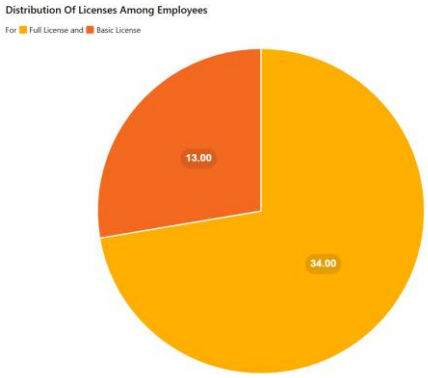


Figure 2
Distribution of Licenses between Full and Basic

This required unplanned procurement to ensure all personnel could perform their roles. Despite this, all 19 configured full license roles and 3 basic roles were successfully tested. Though two minor deviations were noted during the testing of data migration, they were promptly investigated and resolved. The Qualification process concluded with 100% passing rates for all tests, formally validating the system's integrity.

The second major objective—transitioning all training activities—was met through the successful configuration and activation of the eQMS Training Matrix. The QA team and Training Coordinator developed a comprehensive training package, including a fundamental System Use SOP and three Work Instructions for specific user tasks (training module use, creation, and approval). Training completion reports post-Go-Live provided real-time compliance oversight, a feature impossible with the previous manual system.

User adoption has been robust. Initial reports showed a high training completion rate; specifically, of the 712 training activities assigned on September 8, 2025, Go-Live, 413, were completed by September 26, 2025, as detailed in Figure 3.

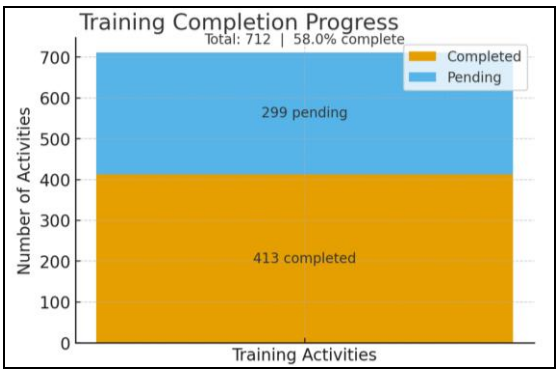


Figure 3
Current Training Completion Progress

Furthermore, user activity in the first 15 working days saw the initiation of 59 new documents. Of these, six were fully approved and released, while the remaining 53 were in process, as demonstrated in Figure 4.

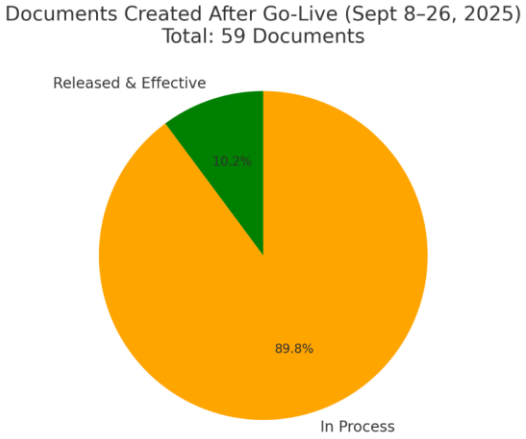


Figure 4
Analysis of Documents Created After Go-Live

This rapid initiation rate validates the successful execution of the entire end-to-end workflow, from creation to final approval.

The digital platform delivered significant efficiency gains compared to the manual system. The time required for an individual to complete and record a training assignment was reduced from an average of five business days to less than one hour, a substantial decrease from an estimated 40 hours to under 1 hour per training activity (Figure 5).

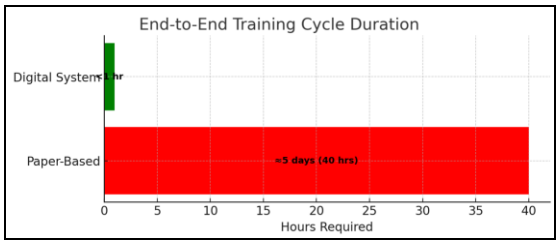


Figure 5
Comparing Training Cycle Durations: Digital System vs Paper-Based

Similarly, the document creation, review, and approval lifecycle was cut from an average of 10 working days to 5 working days (Figure 6).

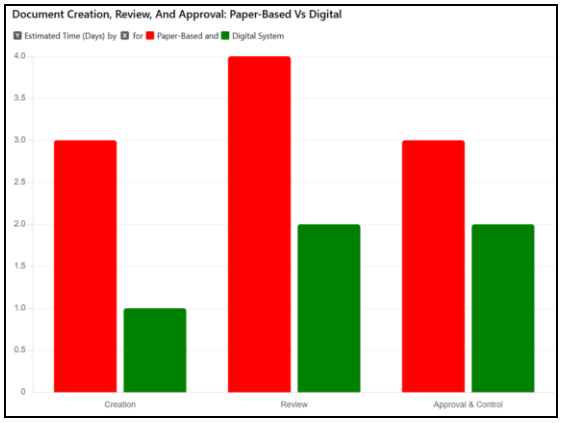


Figure 6
Paper-Based vs Digital Document Creation, Review, and Approval Process

Crucially, the system improved compliance and data integrity by providing a centralized repository, automated audit trails, and secure electronic signature controls that align with FDA 21 CFR Part 11 and eliminate the risks of the previous manual process.

While successful, the project yielded important lessons. The initial timeline proved overly ambitious, requiring more time for configuration and validation than anticipated. Data migration required significant post-upload verification and reconciliation efforts, underscoring the need for more robust pre-migration planning. Furthermore, the underestimation of full license requirements created an unnecessary logistical challenge. The

primary lesson for future rollouts is the importance of strengthening change management: establishing realistic timelines, tailoring training to specific roles, and initiating user preparation earlier to support the cultural shift required for full digital adoption.

CONCLUSION

The implementation of the electronic Quality Management System (eQMS) successfully achieved its primary goal: a complete transition from a high-risk, paper-based system to a validated digital platform. This transformation fully eliminated the inefficiencies and human errors inherent in the manual process. The project successfully completed two critical objectives: the full migration and validation of all 67 controlled documents, which now benefit from automated version control and immutable audit trails, and the complete digitalization of the training program via a Training Matrix that automatically assigns role-specific courses, significantly reducing compliance risk. Following a rigorous qualification phase that resolved minor deviations and concluded with a 100% pass rate, the system was fully operational at Go-Live on September 8, 2025, providing a fully functioning digital quality management system.

The impact of the eQMS on organizational efficiency and compliance has been transformative, fundamentally reducing cycle times across key functions. The average time for an individual to complete and record a training assignment was dramatically reduced from approximately 40 working hours (five business days) in the manual system to less than one hour with the digital platform. This efficiency was immediately demonstrated by the completion of 413 of 712 assigned training activities (58%) within the first 15 working days post-Go-Live. Furthermore, the document creation, review, and approval lifecycle was cut by 50%, moving from 10 working days to 5 working days, thanks to streamlined electronic workflows, automated notifications, and secure e-signatures. Critically, the system introduced immutable audit trails, role-based access, and secure electronic signatures, fully aligning the company's records with FDA 21 CFR Part 11 and CGMP data integrity standards.

Beyond immediate efficiency, the eQMS provides a sustainable and scalable framework for the company's future growth, while also underscoring key lessons learned. The centralized digital repository and automated controls support long-term data integrity and audit readiness, and the system is inherently scalable to expand compliance and document management into other functional areas like R&D and Manufacturing. However, the project highlighted the need for more realistic timelines with buffers for configuration, thorough pre-migration data analysis to avoid discrepancies, and comprehensive upfront assessment of full license requirements (which were initially underestimated). The experience confirmed that change management strategies must be robust, with early, tailored training essential for overcoming user adaptation challenges and ensuring sustained adoption. The successful implementation, despite these challenges, establishes a strong foundation for the company's digital transformation journey.

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