



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

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Abstract

An electronic Quality Management System (eQMS) replaced paper-based document control and training at a regulated biopharmaceutical company. It aimed to improve efficiency, compliance, and data integrity. The initiative successfully migrated 67 controlled documents and digitized 712 training activities, with over 58% completed within 15 days. The eQMS introduced automated workflows, electronic signatures, audit trails, and role-based access controls, aligning with FDA 21 CFR Part 11 and CGMP standards. Training cycle times reduced from five days to under an hour, and document approval improved by 50%. Challenges like license allocation and user adaptation were addressed through strategic planning and stakeholder engagement. The initiative demonstrates the transformative impact of digital platforms on quality management and sets a foundation for future growth.

Key Terms — eQMS, paper based, efficiency, traceability, compliance, and digital platform.

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.

Methodology

The electronic Quality Management System (eQMS) for document control and training will be implemented using a structured, three-stage, eight-phase methodology (see Figure 1: Project Gantt Chart for timeline alignment) to ensure regulatory compliance, user adoption, and system sustainability.

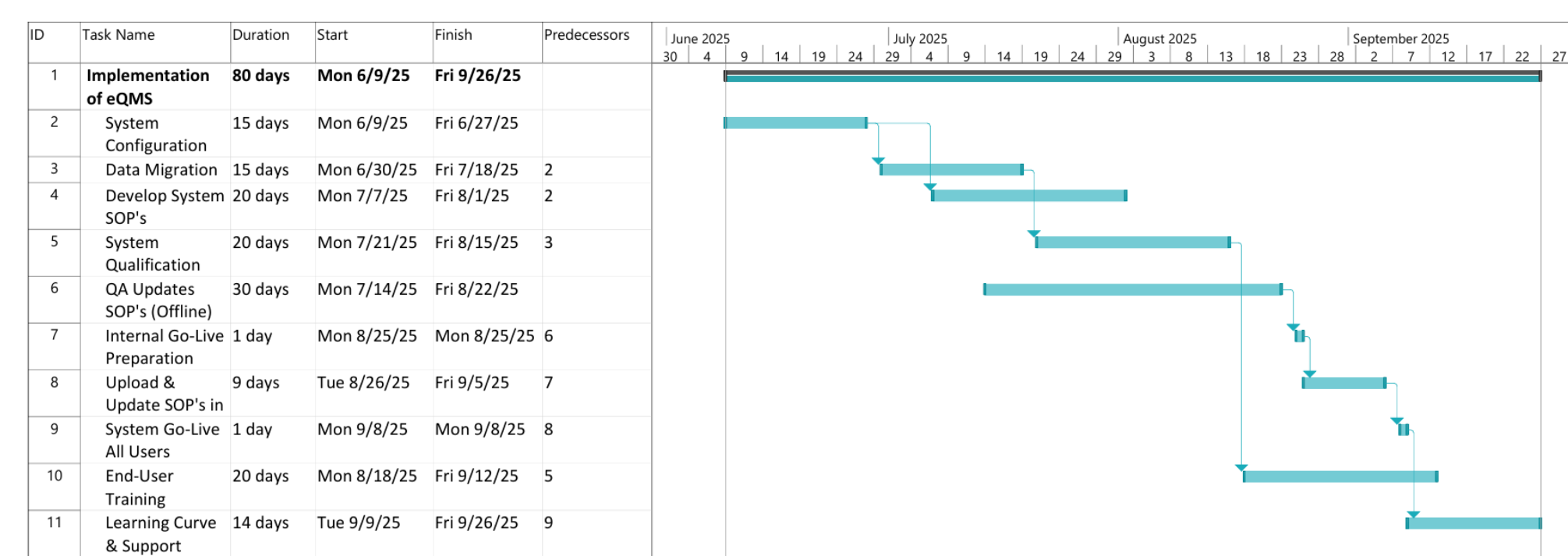


Figure 1: Project Gantt Chart

Stage 1: Initial Setup and Content Preparation (June 9 – August 22, 2025) This stage establishes the system's foundation and prepares content for upload. Phase 1: System Configuration (June 9 – June 27): Define requirements, set document hierarchies, configure role-based access (RBAC), audit trails, and the training matrix framework. Phase 2: Data Migration and Document Setup (June 30 – July 18): Digitize and upload existing SOPs, validating them against original records to establish version control. Phase 3: QA Offline SOP Updates and Creations (July 14 – August 22): 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.

Methodology (Cont.)

Stage 2: System Validation and Training (July 21 – September 12, 2025) This stage focuses on compliance and end-user readiness: Phase 4: Qualification of eQMS (July 21 – August 15): Execute User Acceptance Testing (UAT) and verify electronic signature functionality to comply with FDA 21 CFR Part 11. The main deliverable is a qualification package. Phase 5: End-User Training (August 18 – September 12): QA conducts in-person power-user workshops and system-based training modules for all employees, using the activated training matrix to auto-assign role-specific tasks.

Stage 3: Final Deployment and Support (August 25 – September 26, 2025). The final stage ensures a smooth company-wide transition: Phase 6: QA Final SOP Upload and Review (August 25 – September 5): QA finalizes the upload of all revised SOPs, links them to required training, and closes any open review cycles, resulting in a fully updated SOP library. Phase 7: System Go-Live (September 8): The official company-wide launch activates all SOPs and workflows, enabling real-time reporting dashboards and transitioning the organization to digital operations. Phase 8: Post-Go-Live Support (September 9 – September 26): Provide user support, monitor training completion, and confirm system effectiveness, culminating in a post-Go-Live performance report.

Results and Discussion

Distribution Of Licenses Among Employees
For Full License and Basic License

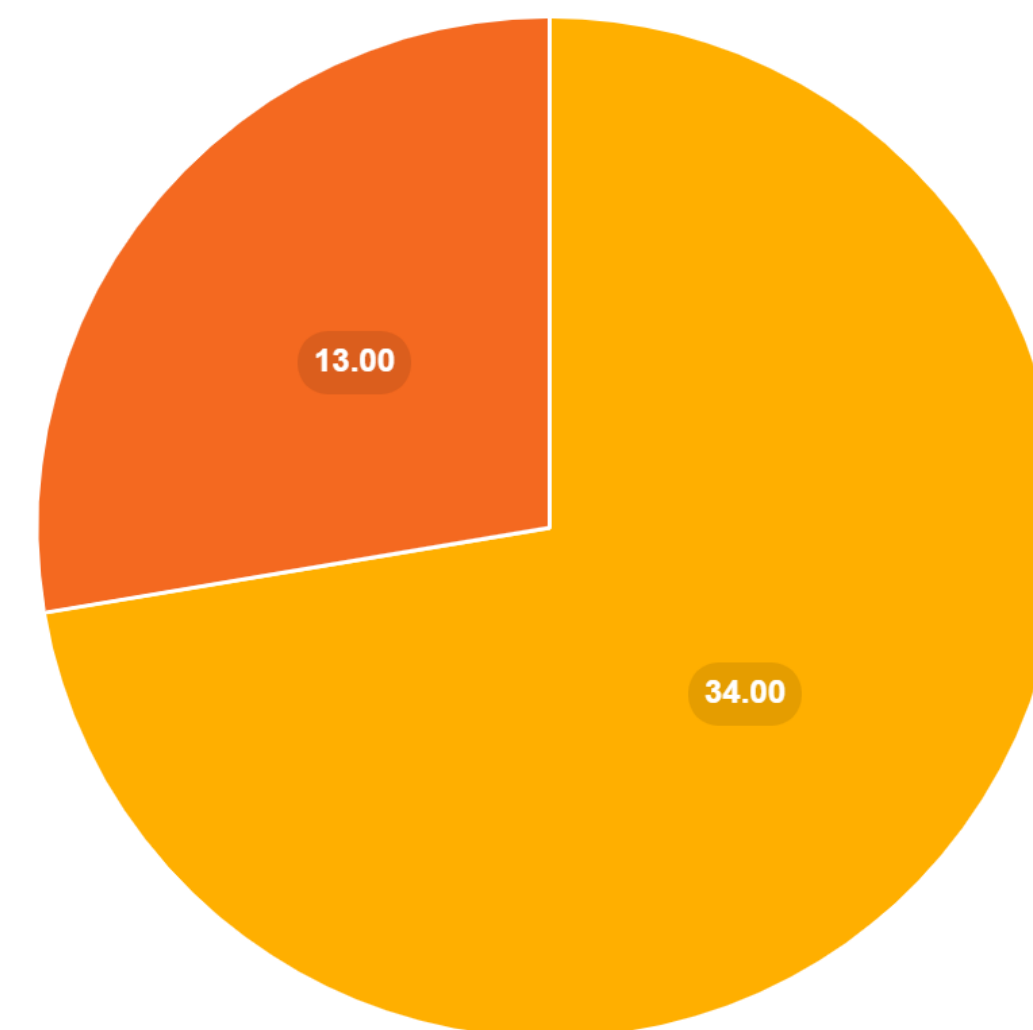


Figure 2: Distribution of Licenses between Full and Basic

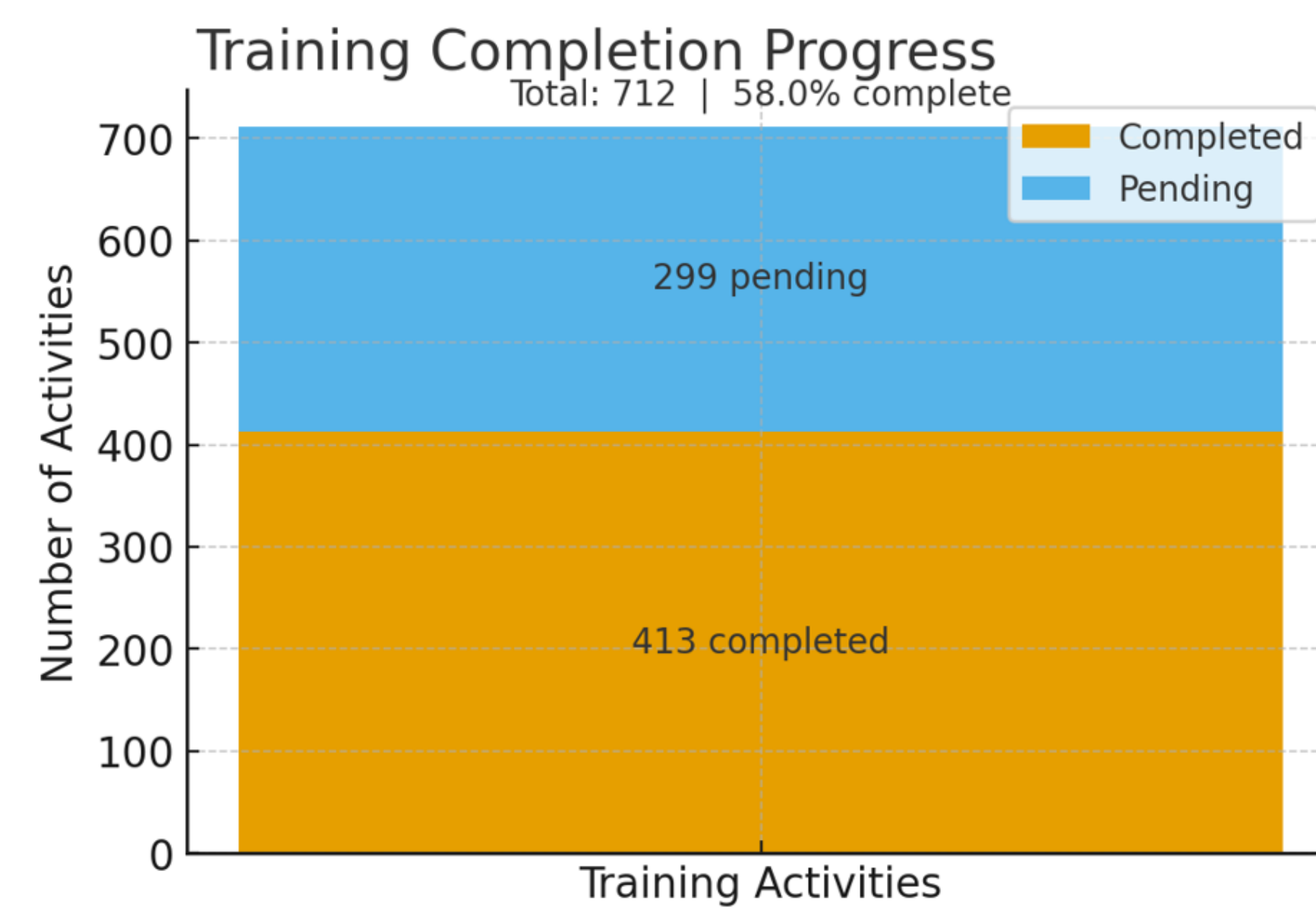


Figure 3: Current Training Completion Progress

Results and Discussion (Cont.)

Documents Created After Go-Live (Sept 8-26, 2025)
Total: 59 Documents

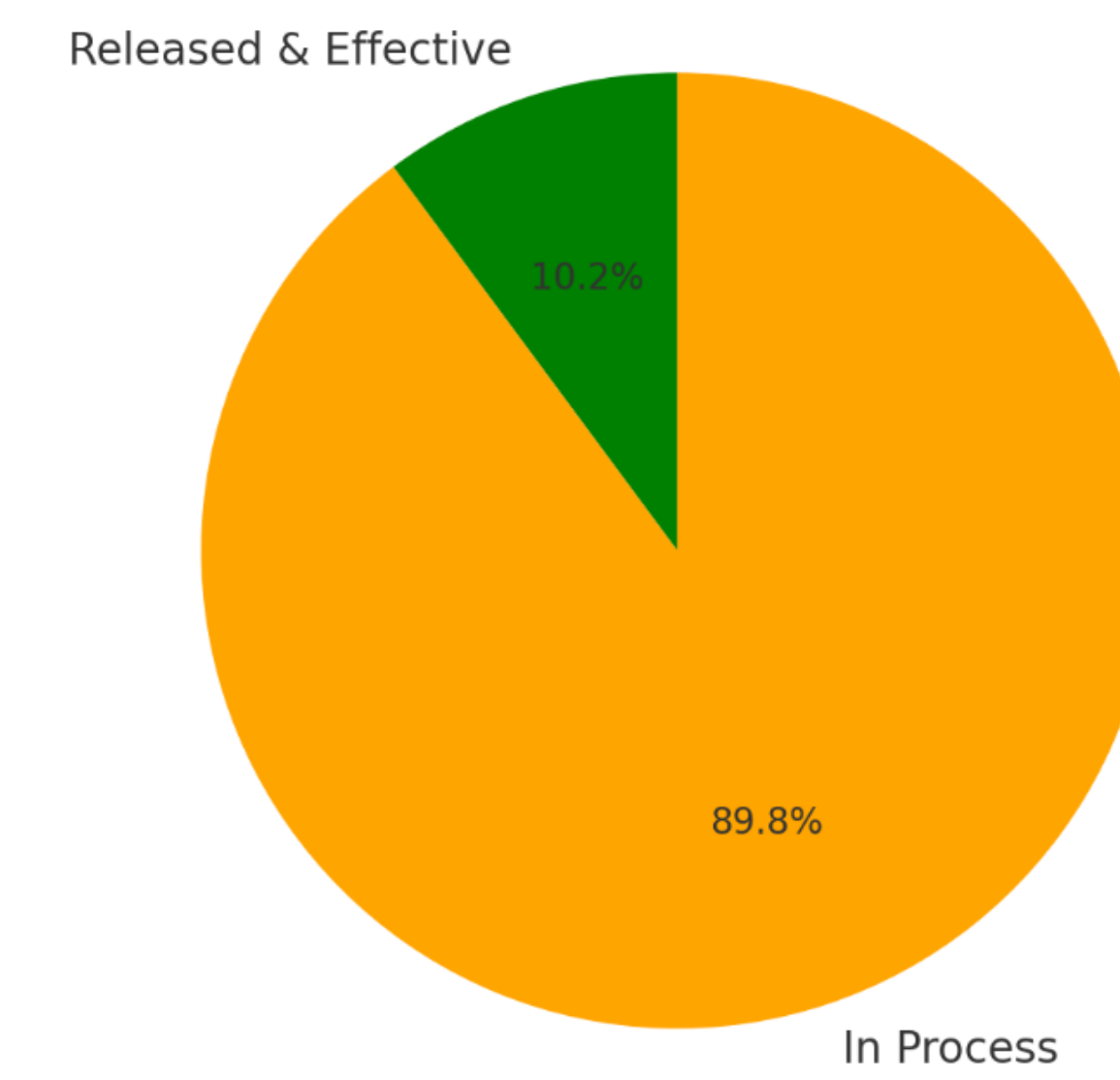


Figure 4: Analysis of Documents Created After Go-Live



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

Document Creation, Review, and Approval: Paper-Based Vs Digital

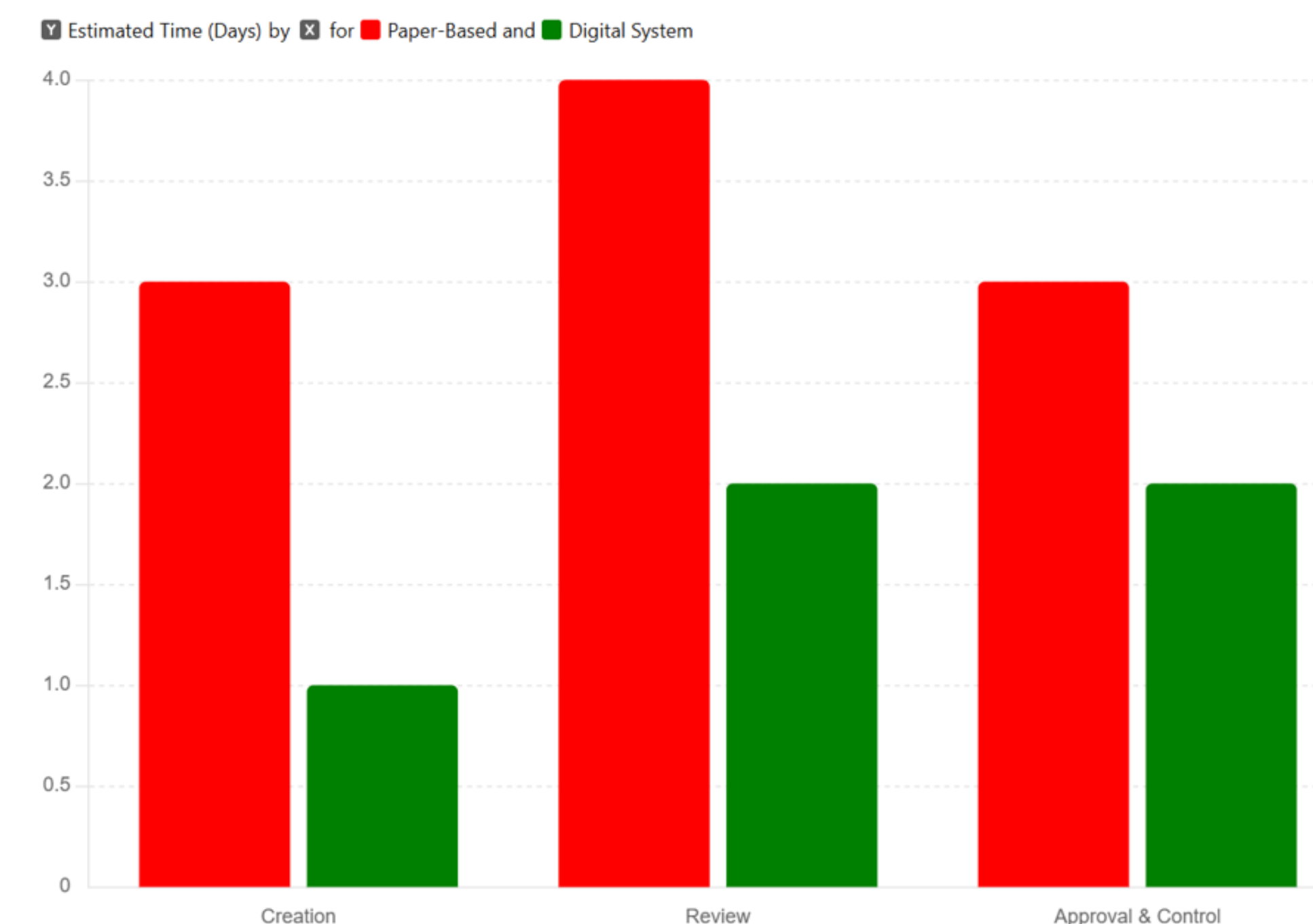


Figure 6: Paper-Based vs Digital Document Creation, Review, and Approval Process

Conclusions

The implementation successfully transitioned the company from a paper-based system to a validated digital platform, achieving compliance and eliminating manual process inefficiencies. The project fully migrated and validated all controlled documents and digitized all training via an automated Training Matrix, resulting in a dramatic reduction of the training completion cycle from working hours to less than one hour and halving the document creation/approval lifecycle from to working days. While the provide a scalable framework with immutable audit trails, key lessons learned for future rollouts include the need for more realistic timelines with buffers, thorough pre-migration data planning to avoid discrepancies, and robust change management strategies to ensure sustained user adoption and address initially underestimated full license requirements.

Future Work

The next phase of this research will focus on expanding the scope of the validated electronic Quality Management System (eQMS) beyond document control and training. The immediate steps are to continue implementing additional eQMS modules. These modules will digitize and automate other critical quality processes, including Change Control, Investigations, Deviations, and Supplier Qualification, establishing a comprehensive and fully integrated digital quality ecosystem at OcyonBio. This continued implementation will further enhance compliance, operational efficiency, and data traceability across the entire organization, building upon the scalable framework established in this project.

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