Implementation of Digital Documentation System as a Replacement for Current Physical Documentation Process

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Abstract

The purpose of this project was to establish a digital documentation system for the site's form execution processes. Physical printing incurs cost for paper and toner, along with slow monitoring of data. The main objective of this project was to convert physical executable forms into electronic forms by creating a digital documentation platform while complying with regulatory governing bodies and standards organizations. By employing a PDCA methodology, the planning and execution of the project was a success by successfully converting 42 forms from physical to digital in the span of two phases, with the remaining 17 forms tied to Phase 3 scheduled to conclude by February 2026. Finally, future projects should finalize the last Phase 3 of the project to further accomplish the site's paperless agenda.

Key Terms* — *Physical Documentation, Digital Documentation Platform, Good Documentation Practices, ALCOA+

Problem Statement

The purpose of this project is to establish a digital documentation system for the site's form executions processes. When it comes to documenting any process, any mistake can lead into major problems like deviations or loss of product. In addition, the current documentation system requires a large amount of work as it takes time to document, review, validate, and identify errors. Additionally, a significant amount of paper is used to document all the processes done on the site. To address this, the site is implementing a paperless agenda that will change the way the plant will operate with a digital documentation system.

Background

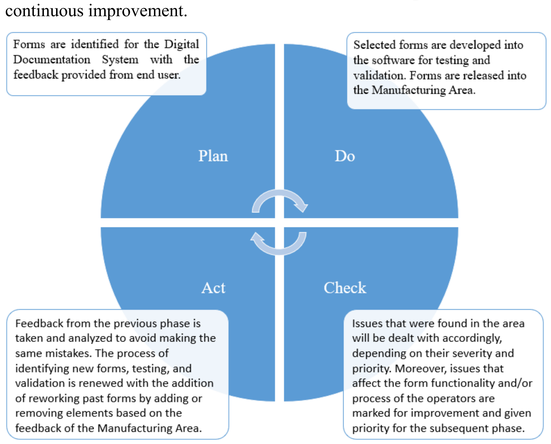
Good Documentation Practices (GDP) are guidelines that must be followed when recording data from a process, checklist, or any other procedure that requires documentation. GDP states the proper way to create, handle, and maintain documents within a company by setting a systematic procedure in which a company prepares, reviews, stores, and archives documents.

ALCOA is cited as the ultimate reference to comply with data integrity in the pharmaceutical industry. Companies must follow the ALCOA attributes to comply with GDP requirements both in Physical and electronic documentation. ALCOA is an acronym for Attributable, Legible, Contemporaneous, Original, and Accurate.

Four more attributes were added to ALCOA to be renamed ALCOA+ to strengthen controls for data integrity: Complete, Permanent, Consistent, Enduring, and Available.

Methodology

The selected methodology tool is the PDCA, which stands for Plan, Do, Check, Act. PDCA is a four-step cycle that stimulates methodical thinking and action, as well as an iterative management method for continuous improvement.



Results and Discussion

I. Plan

Weekly meetings with subject matter experts and operators from the Manufacturing area, Warehouse, Facilities, and Production area, as well as Quality personnel, were held. A pilot phase was initiated with a small number of forms that suited the platform's strengths and avoided its limitations. As a result of the Planning phase, both a SIPOC and a Project Charter were developed to explain in detail the planning process for the project.

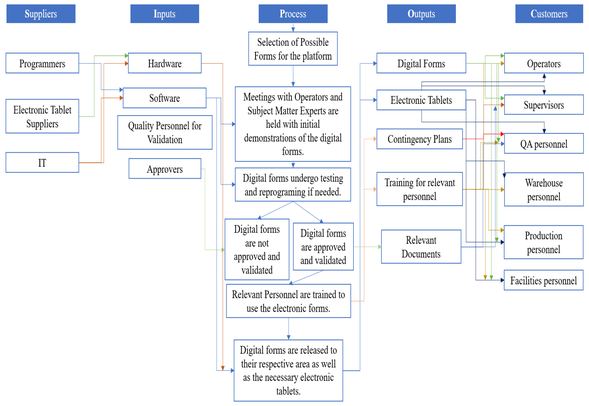


Figure 1: Project SIPOC

Table 1
Project Charter

Project Title: Implementation of Digital Documentation System as a Replacement for Current Physical Documentation Process		
Business Case: Improve the operational efficiency at the site by reducing the reliance on physical printing. This project aims to achieve the site's goal of cost reduction, standardization, and operational excellence.		
Problem/Opportunity Statement: Current documentation system consists of a slow process of data collection and deviation detection that heavily relies on physical printing.		
Goal Statement: Reduce physical printing costs by implementing a digital documentation system to streamline processes, standardize, and increase data accessibility.		
Project Scope: Replace a portion of the total physical forms by replacing the current system with a digital documentation system in the site's manufacturing area and warehouse by February 2026.		
Constraints: Project must be completed within the allocated budget, documents and digital forms must be delivered on time, must comply with company policies, and timelines rely on approver's availability.		
Assumptions: Programmers will deliver forms on time, all resources will be available during the project's timeline, and relevant personnel will be available for feedback.		
PRELIMINARY PLAN		
	Target Date	Actual Date
Start Date:	September 2025	September 2025
PHASE 1	October 2025	October 2025
PHASE 2	December 2025	December 2025
PHASE 3	February 2026	February 2026
Completion Date:	February 2026	February 2026

II. Do

After forms were selected, developers initiated the programming of the platform, considering the feedback provided in the planning phase. The project aims to publish 59 forms divided into three phases. All forms were divided into three phases, as shown in the following graphs.

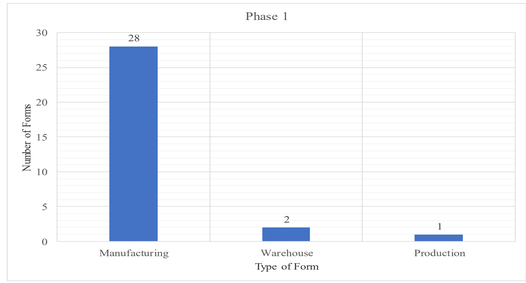


Figure 2: Phase 1 Form Count by Department

Figure 3: Phase 2 Form Count by Department

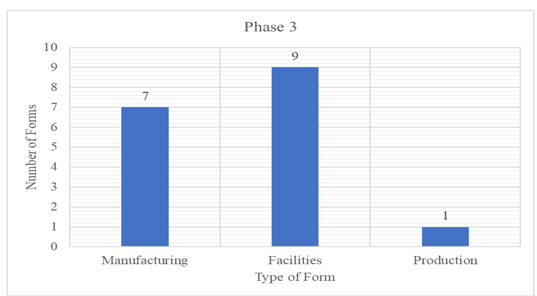


Figure 4: Phase 3 Form Count by Department

III. Check

During implementation, support was provided to the impacted areas of the electronic documentation system. End-user feedback was implemented as soon as it was possible to guarantee the best possible experience. Forms were removed from the platform when these forms were not up to standards or were subject to procedure changes. Forms that required rework were also pulled from the platform and given priority for the following phase.

IV. Act

Further training was imparted when necessary to clear any doubts users may have, as well as demonstrations on the use of the platform. Forms that were proven effective were left as is. New forms were identified for digitalization, renewing the process for a new phase. For forms that were removed, a replanning phase initiates with a priority placed on them. Finally, the stabilization period comes to an end, and the new phase begins.

Conclusions

The purpose of this project was to establish a digital documentation system for the site's form execution processes, following the company's paperless agenda. Physical printing incurs cost for paper and toner, along with slow monitoring of data. The main objective of this project was to convert physical executable forms into electronic forms by creating a digital documentation platform. Moreover, the platform must comply with Good Documentation Practices, ALCOA+ principles, and CFR Part 11 enforced by governing bodies. A Plan-Do-Check-Act was employed as the Methodology to execute the project, divided into three phases. The Plan consisted of weekly meetings with end-users to understand the requirements of each form. Do was comprised of creating, testing, and publishing the selected forms. On Check, the mistakes from the project were identified. In Act, the mistakes were corrected, and forms that were not up to standards were retired and given priority for the next phases. With 59 forms divided into three phases, the project's execution was carried out. Phase 1 and Phase 2 were successfully converted into digital forms with 42 forms in total. Phase 3 is scheduled to conclude by February 2026 with the remaining 17 forms.

Future Work

Future projects should finalize the last Phase 3 of the project to further accomplish the site's paperless agenda. Furthermore, future researchers should study both the positive and negative impacts of the digitization of executable forms.

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