

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

*Gabriel Espinosa Vázquez
Master of Engineering in Manufacturing Engineering
Advisor: Dr. Rafael A. Nieves Castro, PharmD.
Polytechnic University of Puerto Rico
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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 — *ALCOA+, Digital Documentation Platform, Good Documentation Practices, Physical Documentation.*

INTRODUCTION

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.

PROBLEM STATEMENT

To comply with the paperless agenda the site is undergoing, a digital documentation system will be implemented. It is important to note that a digital documentation system will comply with Good Documentation Practices imposed by regulatory government bodies and standards organizations. Why implement a digital documentation system when documentation has always been done on paper? A paperless execution eliminates the use of paper making the site a more sustainable for the environment. Not only that, this type of documentation is done in real time that leads to an acceleration in the documentation process. Also, data integrity will be ensured as a traceable and precise system will be used. Furthermore, the reduction of deviations will be achieved as a digital system will narrow down the source much quicker than normal documentations systems.

The main objective of the project is to create a digital documentation system to comply with the 100% paperless agenda the site is undergoing. This will cover a part of the agenda by focusing on a percent of all the site's executed forms. Within this percentage, a process that will not only create executable forms but also deliver a validation process and implementation process all while taking into account data integrity and establishing controls to ensure its compliance. In particular, the goal of the project is to decrease deviations, increase efficiency of the documentation process, and accelerate processes by creating a digital documentation system to record execution of processes.

With this digital documentation system, the main contribution is to build an efficient process with the creation of paperless executions and real

time documentation. Not only that, the site is looking to reduce the workload of everyone involved. Lastly, by simplifying the process, the site is looking to streamline documentation as well as the review of data. Contamination causes the need to discard entire batches of semi-solid products that may cost significant money and time to the manufacturer.

LITERARY REVIEW

Regulatory agencies establish standard requirements to ensure that pharmaceutical companies follow the necessary protocols to guarantee that procedures for handling their products are safe. Documents detailing the procedure of creation, handling, and distribution of these products provide evidence that a pharmaceutical company followed the standards. Any procedure that was not documented is considered not to have been done. This extends to digital documentation. Governing bodies have created a set of guidelines to facilitate compliance with these requirements.

Good Documentation Practices

Good Documentation Practices (GDP) are guidelines that must be followed when recording data from a process, checklist, or any other procedure that requires documentation [1]. Good Documentation Practices apply to determine whether a product manufactured as type A complies with Current Good Manufacturing Practices to guarantee its safety and that it meets purity and quality criteria [2].

When recording information, data must be legible, traceable, and reproducible for it to comply with GDP standards. 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 [1]. Records can be retained for as long as necessary; however, the standard is that a record must be retained for at least 2 years within a plant or facility [2]. GDP ensures data integrity, which can be defined as complete, consistent, and accurate data throughout its life cycle [3]. To summarize the key

aspects, the ALCOA and ALCOA+ were developed as attributes that comply with GDP requirements.

ALCOA and ALCOA+

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 on paper and in electronic documentation [4]. ALCOA is an acronym for:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate [1]

Four more attributes were added to ALCOA to be renamed ALCOA+ to strengthen controls for data integrity [3]:

- Complete
- Permanent
- Consistent
- Enduring
- Available [3]

Attributable

Attributable means that documents must specify what activity was performed, who performed said activity, the equipment and materials used, and the complete activity logs. If the document possesses multiple pages, attribution must be present on all the pages. Additionally, entries that require it must possess both the signature of the form executor as well as the date. Signatures mean that the signee can perform, verify, and approve the process or step, depending on the position of each individual within a company. This way, the signature identifies and confirms the identity by tracing it to a specific signer. If a digital documentation system is used, an electronic signature can be a unique username paired with a password and the date of the activity the user is signing for. The assignment of each unique username or identifier must also be documented [1].

Legible

For a document to be legible, the wording of said document must be easy to read and permanent. A legible document is necessary to limit misinterpretations when recording a process. This includes handwritten entries, comments, corrections, and signatures, especially when the process requires a reviewer [1].

Contemporaneous

A contemporaneous document requires the signature and exact date and time the data was entered or collected. As backdating, post-dating, and post-dating are not allowed, late entries must always be justified and supported with documents. To ensure the procedure is contemporary, data entries have been incorporated on reports and documents alongside signatures and initials that must be entered when a task is being performed or being reviewed [1].

Original

Original refers to the documentation of first-time raw data properly recorded. These records must be properly maintained as originals, even if the records are transcribed into an electronic system. In this case, electronic documents must reference the original raw data and confirm its completion with accurate signatures and dates [1].

Accurate

An accurate document refers to a reliable record of data with the exact account of events, in which the data makes sense with actual values. Values cannot be approximations; exact values, such as those shown in an instrument used to collect data [1].

Complete

Documents require all information, including all relevant details, to be present on any kind of report. The entirety of the steps in a process must be completely documented to prove the reproducibility to recreate the steps later on. This includes unused spaces, which will require a N/A alongside initials and date [3].

Permanent

All entered data must never be erased nor obscured in any way. In physical documentation, only permanent ink is allowed, and the use of correction fluid is prohibited. On a digital documentation system, the data entered from a process must be stored and retained over time [1] [3].

Consistent

Records must be organized in chronological order and logically ordered. By employing this, the process will make sense across the lifecycle of the data. This guarantees that the process is reproducible and that the documentation process is consistent and adheres to standard procedures [3].

Enduring

Due to a required retention period, data must be recorded on media that lasts as long as its retention period, making it accessible. On an electronic documentation system, the data must be preserved on a system that prevents corruption of the files and must possess backups [3].

Available

Documents must be available for as long as their retention period. Through this, prompt retrieval is readily available when needed by regulators or any employee. Even if the data is uploaded to an electronic record, the data must not be locked away. It must be available when it is needed. When a document is not available, the company risks not complying with GDP standards [3].

C.F.R. Part 11

According to 21 C.F.R. Part 11 [5], electronic signatures are equivalent to handwritten signatures and/or initials. Furthermore, electronic records that adhere to the necessary requirements can be used instead of paper documentation, unless necessary. Also, hardware and software used must be available and subject to FDA inspection [5].

An electronic signature is a digital signature equivalent to a handwritten signature, legally binding to a single individual. This signature can be

any symbol or series of symbols [5]. Nowadays, industry leaders are implementing a unique username and password for each user according to their role and responsibilities within a process. Individuals who handle the creation, maintenance, modification, or transmission of electronic records must employ the required controls and procedures to certify the authenticity and integrity of electronic records for genuine signatures from the signee [5]. Moreover, electronic records must process a time-stamped audit trail that records all events, such as entered data, modifications, signatures, and deletions of electronic records. In addition, modifications of data must not obscure previously entered data. Electronic documents shall be retained for the necessary retention period [5].

The software used for electronic documents must have controls to prevent unauthorized personnel from accessing and, much less, performing, signing, or modifying documents. This can be done by validating the source of data inputs. Finally, users must be held accountable for their actions to discourage signature falsification [5].

RESEARCH METHODOLOGY

In this chapter, the research methodology will be presented in detail. 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 [6].

The methodology consists of:

- Plan: define and gather relevant data for the problem at hand.
- Do: implement a small part of the formulated plan.
- Check: examine the results of the implementation by comparing predictions with outcomes.
- Act: analyze the results to determine if it proves effective or if a replanning phase is necessary [6].

Plan

Discussions with Subject Matter Experts and operators helped identify issues with the current documentation system. Physical documentation has led to slower procedure completion, a higher percentage of human errors, and delays in the process of identifying deviations. Following the paperless agenda the site is undergoing, a digital platform documentation system was selected. After understanding the functionality, capability, and limits of the software, forms were identified for digitalization. A small number of them were chosen for a pilot project to examine the behavior of this platform in the Manufacturing Area. In addition, an assessment of the area must be conducted to determine the number of electronic tablets required for each room.

Do

The development starts with input from operators and Subject Matter Experts. The selected forms are developed into the software for testing and validation. After changes and approvals are made, the software for the selected forms is then implemented into the Manufacturing area, as well as the determined number of electronic tablets in each room. Additionally, proper training is given to the personnel who will work with the digital forms. Finally, a stabilization period is required for the implementation of the new documentation system.

Check

During the stabilization period, feedback from operators is always considered. Issues that were found in the area will be dealt with accordingly, depending on their severity and priority. Moreover, issues that affect the form functionality and/or process of the operators are marked for improvement and given priority for the subsequent phase.

Act

Feedback from the previous phase is taken and analyzed to avoid making the same mistakes. The process of identifying new forms, testing, and validation is renewed with the addition of reworking

past forms by adding or removing elements based on the feedback of the Manufacturing Area.

RESULTS AND DISCUSSION

This chapter presents the discussion of results of the PDCA stated in the previous chapter. Results of the project’s execution are displayed in detail supported by tables and figures.

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. These meetings proved fruitful as both operators and subject matter experts shared their concerns and provided feedback on future procedures to be executed on the digital platform. 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 Project Charter and a SIPOC were developed to explain in detail the planning process for the project.

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

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.

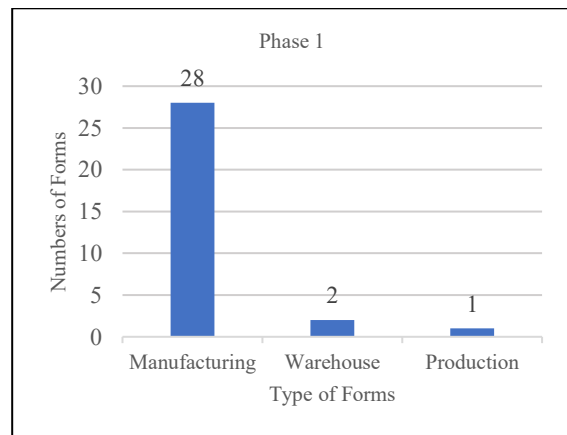


Figure 2
Phase 1 Form Count by Department

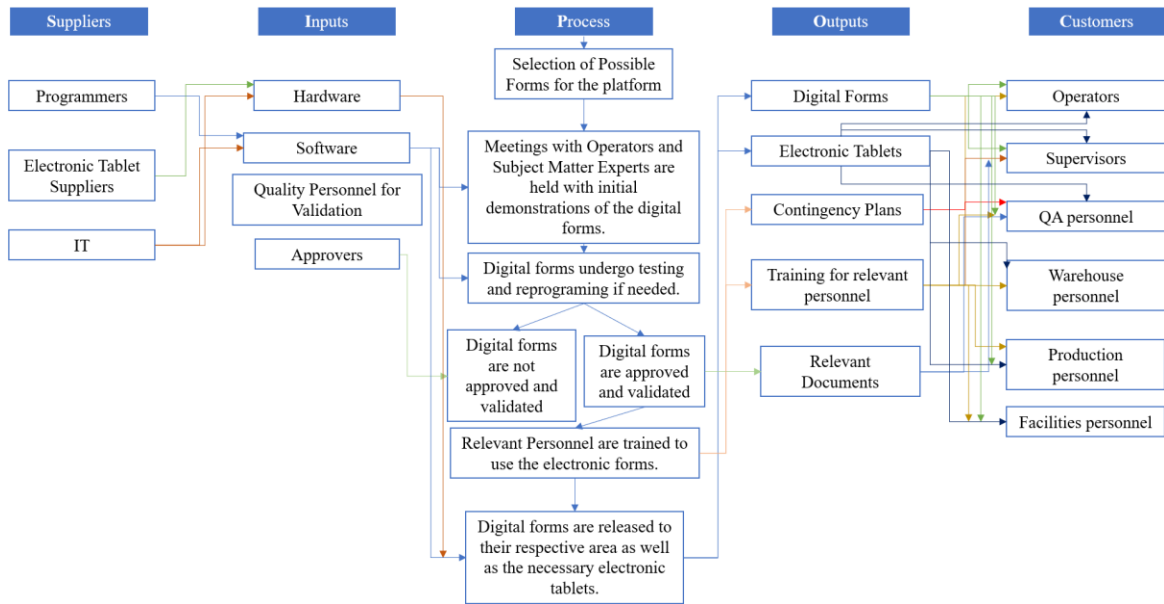


Figure 1
Project SIPOC

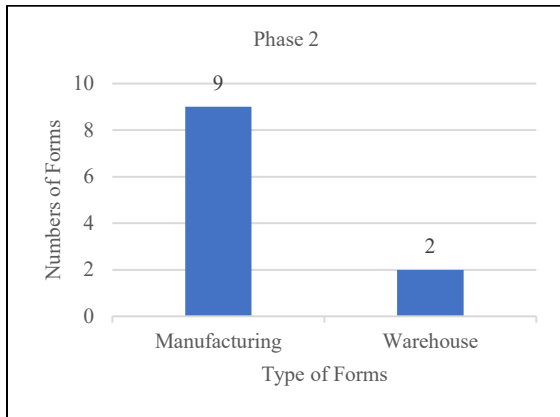


Figure 3
Phase 2 Form Count by Department

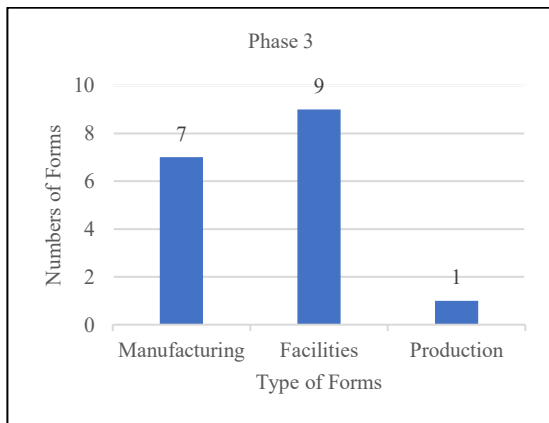


Figure 4
Phase 3 Form Count by Department

The developers programmed the platform to ensure it complies with data integrity and ALCOA+ principles using an agile methodology. Users are given an Operator role, a Supervisor role, or a Quality role under the platform to perform required signatures depending on their role in the company and the form they are filling out. Users of the platform are required to use their usernames and passwords to log in the system and to carry out their electronic signatures complying with ALCOA+ principles.

Table 2
Application of ALCOA+ Principles in Electronic Documentation System

ALCOA+ Principle	Description
Attributable	Activities and events are traced since the moment users log in. Users are given a unique pair of username and password to log in and perform signatures that are traced to the account holder.
Legible	Developers added detailed instructions to each step and added necessary feedback to ensure maximum clarity in each step.

ALCOA+ Principle	Description
Contemporaneous	The system captures all events and entered data at real time.
Original	Data entered stays as the original data, as the electronic record will, in time, be the primary method of documentation.
Accurate	The platform possesses an Audit Trail which offers reliable data recorded with the exact accounts and events documented by users.
Complete	Audit Trails provide everything done in real time by the user or multiple users in the execution of an activity.
Permanent	Even if corrections are made, Audit Trails provide static and permanent data that was entered by users at real time.
Consistent	The platform ensures reproducibility by offering consistent data in chronological order as the user executes a form.
Enduring	The electronic record follows the company's record retention policy.
Available	Both users and regulators have the option to view the records at any time.

Testing and adjustments were made along the way to verify the platform's behavior in the manufacturing area. Subsequently, forms were released into the manufacturing area and given a stabilization period during implementation. Furthermore, training was provided by a designated team of instructors. Training consisted of demonstrations and hands-on practice for every user. Finally, assessments were made to ensure enough electronic tablets were delivered to the impacted areas.

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.

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. Finally, future projects should finalize the last Phase 3 of the project to further accomplish the site's paperless agenda.

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