Reducing Documentation Errors by Designing a Continuous Workflow for the In-Process of Spinal Needles

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Abstract

Good Documentation Practices are essential to maintain a robust Quality System. Many documentation errors were constantly found on acceptance records at the Product Release-to-Packaging stage. A Flow Diagram and a Root Cause Analysis were performed to identify deficiencies on the process that were leading to errors. Four different types of wastes were found multiple times in the in-process of spinal needles, constantly interrupting the flow of work and information. A continuous flow is achieved by re-designing the in-process documentation. The new acceptance record avoids most of the documentation mistakes by replacing handwritten forms with electronic forms, ultimately, improving productivity and achieving a leaner process.

Introduction

In the Manufacturing Industry, both Quality and Operations departments enforce the importance of following Good Documentation Practices to avoid compliance issues. Despite efforts, documentation errors are still an important problem that creates a bottleneck in the production process of spinal needles. The purpose of this research is to identify what is the root cause of finding documentation errors on the last step of the process. Both manufacturing and quality processes will be studied to find irregularities that can be affecting the employee's performance. Reducing errors will achieve a smooth flow from sub-assembly to packaging, adding value to the process. Lean Manufacturing techniques can be helpful to effectively provide a complete overview of the process and identify flow disruptors.

Background

- In the health care industry where errors are critical, results have consistently demonstrated that implementing electronic records helps reducing documentation errors and decreases the number of medical errors associated with them. Also, waiting time is reduced because of improving the system workflow. [1]

- Author Bryon Hayes wrote about the multiple benefits of implementing automated systems such as the Electronic Batch Record in the manufacturing industry: "EBR systems remove the (error-prone) humans from the record-keeping equation, enhancing data integrity and speeding up the batch release process. Quality assurance (QA) personnel are no longer needed to parse binders full of paper prior to signing off on a batch of drug product" [2].

- Author Hari Agarwal elaborated on the lean documentation topic by creating a guide to determine whether documentation is necessary or if it is duplicated information [3].

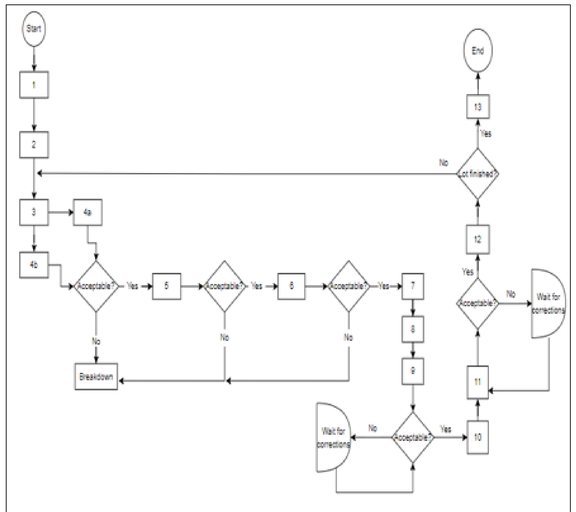
- The use of focal groups and direct observation helped to identify and reduce wastes within the documentation process resulting in a 37% decrease on documentation time. [4]

- Authors Ghuge and Gaundare, found that: "Detecting the root cause of any kind of problem is very important to eliminate wastage and to make process flow optimum" [5].

Methodology

Lean methodology focuses on achieving a continuous flow of value. Direct observation of the in-process of spinal needles from the TIC machines for every shift was used to map the current process.

Current Process Workflow

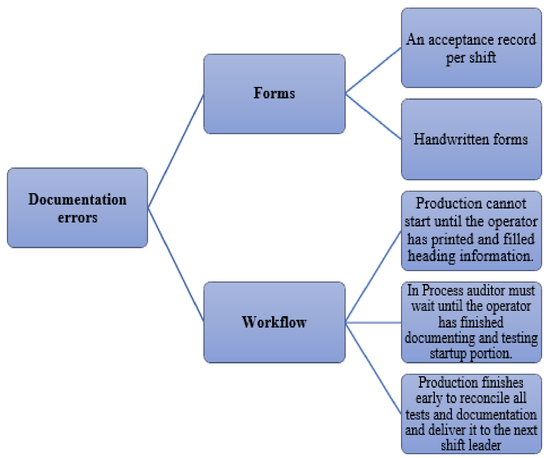


1. Fill in information of Line Clearance form and print.
2. Perform "Prueba de la cruceta" and line clearance activities.
3. Fill in information of "Inspeccion de Proceso" and print.
4. a. Print Parameters
   b. Perform Usable Length test
5. Perform tests
6. Perform Visual test hourly
7. Take "Inspeccion de Proceso" form to shift leader's desk at the end of shift.
8. Next shift leader verifies form.
9. Leader completes Checklist form.
10. Take document to Quality Inspector's desk.
11. Next shift Quality Inspector verifies document.
12. Archive document in S3(QA inspector) desk.

Repeat steps 3-12 (10 steps) until lot is finished (Usually it takes up to **four** shifts).

13. Quality Inspector releases for packaging.

A tree diagram was performed to summary important findings



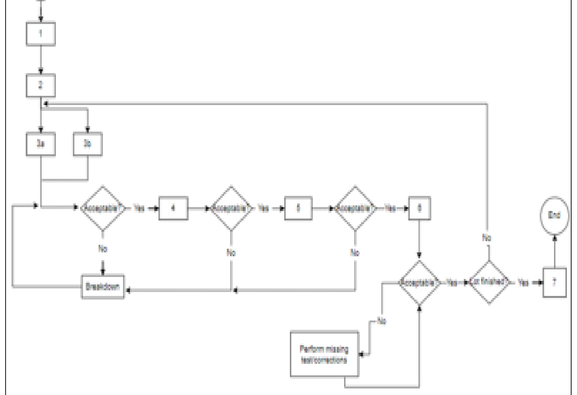
Results and Discussion

A Five Why Diagram was performed to find the Root Cause of documentation errors. A discontinuous flow of value was identified as the Root Cause. The only value adding activity in this process, which is the production, is constantly being interrupted or delayed because of unnecessary steps and the inefficient workflow design.

Five Why Analysis

- **Problem** • **Many documentation errors are found during the Product Release to Packaging stage.**
- **Why** • Daily documentation audit is performed anywhere from the end of shift to the end of lot. There is no standardization which makes it non efficient.
- **Why** • Each shift has their own acceptance record which interrupts the the production and information flow.
- **Why** • Production activities cannot start until the operator has finished printing and filling the acceptance record which is time consuming. Production also finishes early to reconcile and deliver documentation to the shift leader's desk.
- **Why** • Documentation is mostly hand-written and repetitive.
- **Why** • **The workflow is discontinuous.**

New Workflow Design



1. Fill information on new document "Inspección de Proceso".
   The new document will be used by all shifts and includes the line clearance.
   Handwritten tests are replaced by E-forms.
2. Perform "Prueba de la Cruceta" and line clearance activities.
3. a. Print Parameters
   b. Perform Usable Length test.
4. Perform tests using e-forms.
5. Perform visual tests every hour.
6. Quality Inspector goes to each machines' desk to verify document.
   A quality inspector will verify for completeness and GDP by the second hour after shift start up.
   Corrections can be made immediately.

Repeat steps from 3-6 (4 steps) until lot is finished.

7. Quality Inspector releases for packaging.

Conclusions

The proposed solution consists of designing an acceptance record that once issued at the Line Clearance, can be used by every shift until the end of lot. To be able to do this, it was necessary to remove tests forms from the acceptance record. Manual entry tests were replaced by electronic forms which not only shortens the documentation time, but also avoids entry errors, missing information and reporting wrong values. E-forms contain the acceptance criteria data to automatically compare them to the obtained values and report results. The unnecessary reviewal steps were replaced with one in-process documentation audit by a quality inspector once the testing process has finished. This design allows the process to flow continuously, eliminates interruptions and reduces the delay and transportation wastes from the current process. The proposed project effectively eliminates 24 activities that were disrupting the flow of value. A student T distribution was performed to test a hypothesis based on how the new electronic forms will reduce significantly the testing time. The new process demonstrated to reduce inspection time by almost half of the current process.

Ho: μ a	EQUALS TO	μ b
Select one 1 = YES	MORE THAN	LESS THAN NOT EQUAL
H1: μ a	MORE THAN	μ b
Test with Unknown Variance (Student T Distribution)		

Hypothesis Test Results	Current (a)	New (b)
Mu	62.41	37.76
Std. Dev.	7.2	2.6
X Bar	62.4	37.76
N	10	10
T exp	10.15	
V	11.0	
Pvalue	0.0000003	
Alpha	0.05	
Mu A is more than Mu B		

Future Work

Future projects include the analysis of other areas to implement the same workflow. The priority must be the packaging area where records are also performed by shift. This could dramatically reduce the unnecessary copies and the final DHR size.

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