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.*

Key Terms *— Continuous Workflow, Good Documentation Practices, Lean Manufacturing, Root Cause Analysis.*

INTRODUCTION

Good Documentation Practices constitute an important building block of a healthy Quality System. Regulations establish the requirements for documentation ranging from the Device Master Record (DMR) to Standard Operating Procedures and records. Acceptance Records are used to provide evidence that the output of an operation was performed following the directions stipulated by the DMR. In the Manufacturing Industry, both Quality and Operations departments enforce the importance of following Good Documentation Practices to avoid compliance issues. An error in a quantity, forgetting a signature, or omitting a test value, can all cause events that might end with the discard of good, finished product, and even a recall if there is no evidence of conformance.

Some organizations provide constant re-training of GDP to make employees aware of its importance. Other initiatives include adding review steps to every operation, most of the time by a Quality Inspector. However, a modern approach to Quality Assurance suggests that monitoring activities constitute a waste or muda which stops the process from being optimum. The reasoning behind this approach is that constant monitoring activities are unnecessary when a process runs efficiently; efforts must aim for prevention, rather than correction. Documentation errors are still an important problem that creates bottleneck in the production process. This research analyzes the production process of Spinal Needles to find the root cause of documentation errors and provide a solution.

A Spinal Needle unit consists of a stylet attached to a handle, which is assembled by a TIC machine to a cannula attached to a hub and secured with a shield. This process runs automatically and has a setup responsible to feed the machine with material. The setup is also responsible for the issuance of the acceptance record that includes machine start-up activities and in-process inspections. These inspections are performed by an 'in-process auditor' responsible for completing visual, functional, and dimensional testing. The process requires a sample of 16 units at every shift startup for visual and a set of nine tests. After startup, the auditors are required to sample four units hourly only for visual inspection. Every shift has one setup for each of the five TIC machines, and two in-process auditors. This is a total of 15 setups and six in process auditors for the three eight hours shifts first, second, and third. Once the shift ends, the acceptance record is verified for completeness and GDP by a manufacturing leader,

and subsequently reviewed by a Quality Inspector. The latter is responsible for holding every acceptance record of every shift until the lot is finished. Once finished, it gets reviewed a third time by another quality inspector to perform a product release to packaging.

During the third review, inspectors were facing many important situations including documentation errors and lost or misplaced acceptance records. It is important to mention that a lost record implies to discard an entire shift production due to the lack of specification's conformance evidence. Errors found that far on the process require corrections, if GDP related, or opening a Quality Event investigation, if related to a missing test or important information. In case the responsible for the correction is not present, the whole release process must wait, delaying the start of the packaging, final product release, shipping, and delivery activities.

It is evident that the first and second review processes are failing to identify and correct errors on time. However, on the second review they still correct an important number of mistakes, but they can only audit documentation from pasts shifts. There is no in-process verification of the records which complicates the outcomes of missing information or a test. Corrections cannot be performed immediately and must wait for many hours and in some cases, multiple days. The documents waiting for corrections accumulate on the area, increasing the probability of getting misplaced or mixed up. The first review is performed at least two hours after the end of shift which implies the same consequences mentioned above. This review is performed by a manufacturing leader, who does not necessarily possess the technical expertise to identify errors effectively. Also, the leader has many other important functions, so this process gets rushed most of the time, ignoring its criticality.

The purpose of this research is to identify primarily what is the root cause of finding documentation errors that far on the process. This assessment will also determine why the review process is not efficient. 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 of 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. These disruptors are most of the time hidden wastes on the process that are being ignored by management because production numbers are still achieved.

LITERATURE REVIEW

The Code of Federal Regulations compiles the rules established by the Federal Government. It is divided into titles, parts and subparts, and ranges from general provisions to wildlife industries. The 21 CFR Part 820 Subpart M provides information about the required records in the medical device industry. Device History Records are mentioned in section 820.184: "The DHR shall include, or refer to the location of, the following information: (a) The dates of manufacture; (b) The quantity manufactured; (c) The quantity released for distribution; (d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR; (e) The primary identification label and labeling used for each production unit; and (f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used" [1]. This research focuses on the acceptance records, and how the information flows from assembly to product release for packaging. Once the acceptance records are implemented, monitoring and control measures are needed to ensure compliance. Data integrity uses the ALCOA plus method to guarantee that the data is attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available [2].

The importance of Good Documentation Practices has been widely studied especially in the health care industry where errors are critical. The

article “The effectiveness of EMR implementation regarding reducing documentation errors and waiting time for patients in outpatient clinics: a systematic review” analyzes the results from a selection of articles on reducing documentation errors after implementing an Electronic Medical Record [3]. EMR has been increasingly adopted in the industry as paper-based documentation has shown to decrease health care quality by causing both medical errors and increased patient waiting time. Results consistently demonstrated that implementing electronic records helped by reducing the documentation errors and decreasing the number of medical errors associated with them. Also, waiting time was reduced because of improving the system workflow.

There seems to be a direct relationship between documentation practices and workflow. 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” [4]. So far, studies have provided evidence that changing to an electronic based documentation not only reduces errors but optimizes the workflow and could potentially reduce costs by decreasing the number of employees needed to perform the activity. It is evident that paper-based documentation is the cause of many hidden wastes in the process such as defects and delays due to the verification process.

Author Hari Agarwal elaborated on the lean documentation topic by creating a guide to determine whether documentation is necessary or is just a duplication of information [5]. He also described the importance of providing adequate training to employees as a requirement to improve documentation systems. Lean documentation was also studied on the article “Applying lean methodology to improve parenteral chemotherapy and monoclonal antibody documentation processes based on Normalization Process Theory” [6]. By using focal groups and direct observation, authors were able to identify and reduce wastes within the documentation process resulting in a reduction of 122 ± 8.6 minutes per day and a 37% decrease on documentation time.

The article “Ease of Decision Making Through Process Flow Optimization – A CEAT Way” by authors Ghuge and Gaundare, states that: “Detecting the root cause of any kind of problem is very important to eliminate wastage and to make process flow optimum” [7]. To recap, paper-based documentation is the potential source of numerous wastes found in many processes. Identifying and reducing these wastes can improve and speed the process flow, decrease incidence of documentation errors, and reduce manpower and costs. To do so, it is necessary to perform a root cause analysis and implement preventive actions.

METHODOLOGY

Lean Manufacturing

James Womack and Daniel Jones introduce their book with the definition of muda, a waste or non-value adding activity and proposing the “lean thinking” as the “antidote” [8]. Lean methodology focuses on achieving a continuous flow of value. By using direct observation, the in-process of spinal needles from the TIC machines will be studied for every shift (first, second, and third). There are five TIC machines in charge of molding and assembly parts: hub, cannula, stylet, and shield.

The in-process inspection of spinal needles at the TIC machines consists of visual inspections of finished product along with nine different tests performed at every shift startup. Line clearance activities are performed by each machine’s operator, and two in-process auditors per shift to perform visual, dimensional, and functional tests. Integrating lean tools to this research will help to correctly identify and find solutions to the root cause of the problem statement.

Documentation

A documentation error could be as simple as an illegible entry and as critical as missing a test. Only two out of the nine tests are performed using electronic forms; the rest are documented manually on the acceptance record for each shift. As stated before, paper-based documentation is a major source of errors. The analysis for the acceptance records will focus on elimination of repetitive information such as acceptance criteria that can be added to electronic forms. E-forms provide the benefit of automated formatting and calculations which will ultimately reduce the probability of errors. All Standard Operating Procedures and Work Instructions will be analyzed to ensure that the development of electronic forms is suitable for this process.

After this assessment, manual entry tests will be taken out from the acceptance record to be able to create e-forms for each test. Using Microsoft Excel with the "IF" function to compare the sample value against the acceptance criteria to determine whether a specific sample "Passes" or "Fails" the test. Conditional formatting with a color coding will also be added as a visual aid to react immediately to out of specifications results; green for "Pass" and red for "Fail".

Workflow

A Flowchart or Process Map will be used to identify the wastes associated to this process and provide an insight on the root cause of the problem. A Flowchart consists in a pictorial description of the current process events. Once wastes and the most probable root cause are identified, improvement measures will lead to the creation of a Future State flow diagram.

Root Cause Analysis

As learned from the previous section, documentation errors are considered a waste in the form of defects. These cannot be reduced or eliminated without identifying the underlying cause. A root cause analysis will be performed to find the most probable root cause by using a tree diagram and confirming results with a Five Whys or Why-Why diagram. The idea behind a tree diagram is to breakdown the problem into smaller parts and understand the hierarchy that leads to the undesirable event [9]. A Why-Why diagram analyzes the problem backwards to understand where it starts or why it is happening.

Results And Discussion

Current State

The complete assembly process was observed for five consecutive days on the first and second shift. Direct observation of the third shift process only included startup activities and end of shift for five days as well. The workflow was consistent on every shift; a description of the process is seen below on image 1. The process began at the start of lot with a line clearance, documented on 'form A', that must be printed and filled by the machine set-up operator before performing the required activities. The next step consisted of printing and filling the Acceptance Record 'form B'. The machine operator sat on a desk to fill heading information including the lot number which was repeated at the top of every page of the document. It was observed that production could not start until the operator finished documenting. Once finished, he performed start up activities such as reviewing and printing parameters and performing the usable length test.

After the machine operator accepted both parameters and test results, the in-process inspector took a sample of 16 finished needles, four per molding cavity. The next step consisted of a visual inspection and nine different tests including functional and dimensional. The tests are found on the Acceptance Record in the following order: leak test, effective length, ISO luer taper, shield separation force, handle hub separation force, cannula pull test, stylet pull test, angularity, and alignment. However, it was observed that this order cannot be followed as some of the tests are destructive. The inspector was seen going back and forth through the document to be able to write

down tests results. Both leak test and angularity use electronic forms which automatically returns acceptance results. The rest of the tests are entered manually. Another important observation was that the alignment involved a set of two tests and a calculation. The inspector first measured the cannula and stylet alignment individually and then performed a subtraction between both to find the relation. Since this test results could be negative or positive values all the inspectors observed, left this calculation to be performed at the end of the whole process. This behavior violates the Good Documentation Practices and the ALCOA contemporaneous rule by documenting critical test results after it was performed and not while performing. In the case that a sample fails the relation test, more products will be put on hold until investigation

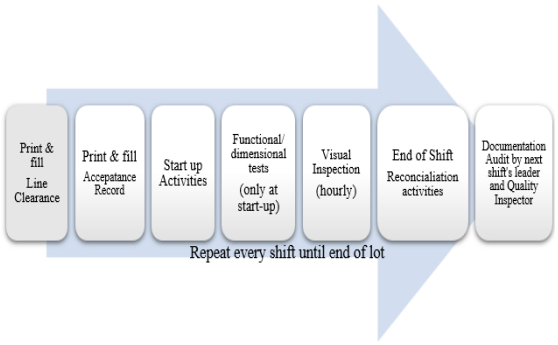


Image 1

In Process Information & Inspection Workflow

Functional and dimensional tests are only performed at every shift start-up, once finished the inspector will inspect only four needles hourly. Production is stopped at least one hour before the end of shift to be able to reconcile documentation. Before leaving, the operator must take the Acceptance Record to the next shift manufacturing leader's desk. The leader reviewed the Acceptance Records for GDP and completeness for each of the five TIC Machines. If any error is found, including missing information, it must be addressed the next day until the operator or inspector is back to work. Once the leader finishes the review, usually took about four hours, they filled a checklist for each document including a heading with the same information that is already on the acceptance record. The document travels to another desk to be reviewed again and archived by a Quality Inspector. Although they are instructed to audit documentation that same day, this depends on what time the records were received. This means that in some cases the acceptance records were reviewed within five hours after the end of the shift but sometimes, they were reviewed more than a day later. After an acceptance record is approved by a quality inspector, it is left on a file until the production lot is finished. The quantity of these batches is most of the time 32,000 needles, which takes approximately four shifts to complete if the process runs without a breakdown. Once the lot is complete, the file is taken to another quality inspector to release for packaging. This process involves yet another review of each already approved acceptance record.

After two reviews of the acceptance record, it is expected to find no errors at all. However, the quality inspectors at the product release stage are still finding an important number of mistakes and missing information. Table 1 summarizes the most common errors found on product release during a month period. Missing information in this case was related to a signature or date. Wrong entries were observed on the equipment and calibration due date for tests, while illegible entries were found in every stage especially in tests results by the in-process auditors.

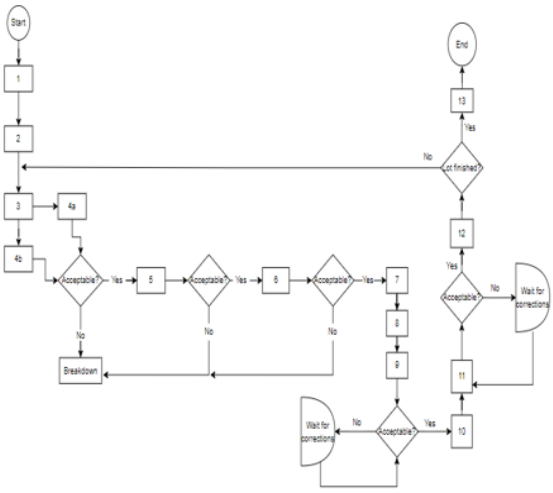
Table 1

Common Errors Found at Product Release

Error	Operator	In Process auditor	Quality Inspector	Total
Missing information	2	1	1	4
Wrong entry	1	0	1	2
Illegible entry	2	4	0	6

Image 2 presents a Flow Diagram of the current state. It shows 13 steps of which ten are repeated approximately four times for every shift, for a total of 43 steps each lot. Many wastes can be seen on the diagram that are affecting this process. Delays due to the multiple approval steps are

identified continuously in the process. The unnecessary documents and repetitive entries are causing extra-processing. By moving the acceptance records from three different desks that are scattered around the manufacturing room, creates a transportation waste. The combination of the previously mentioned wastes is affecting the performance and motivation of the personnel, creating fatigue, and ultimately producing many defects in the form of data entry errors.



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.

Image 2

Detailed Flow Diagram of the Current State

Root Cause Analysis

The tree diagram on Image 3 was performed to find the possible causes of documentation errors. The two broad causes identified were the forms and the workflow. The forms are a problem mainly because they are paper-based and performed by each shift. Paper-based and manual entries increase the probability of human errors which is multiplied on every shift until the end of lot. The workflow was observed to be constantly interrupted: at the start and end of shift and at the multiple documentation reviews.

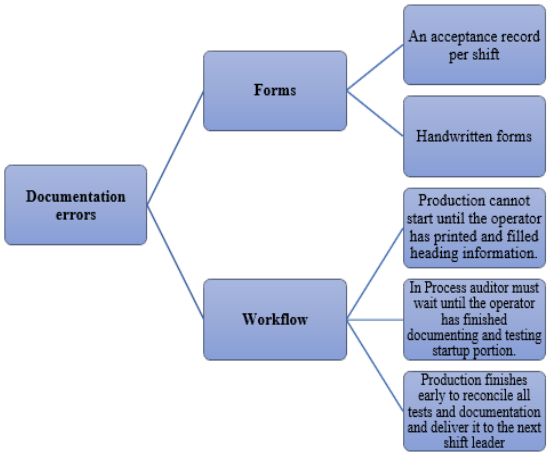


Image 3

Tree Diagram

Both forms and workflow are identified as major problems in the process. A Five Whys Diagram was performed (Image 4) to narrow the results and identify the Root Cause. The final 'Why?' or the Root Cause identified was that documentation errors are due to a discontinuous flow of value. 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.

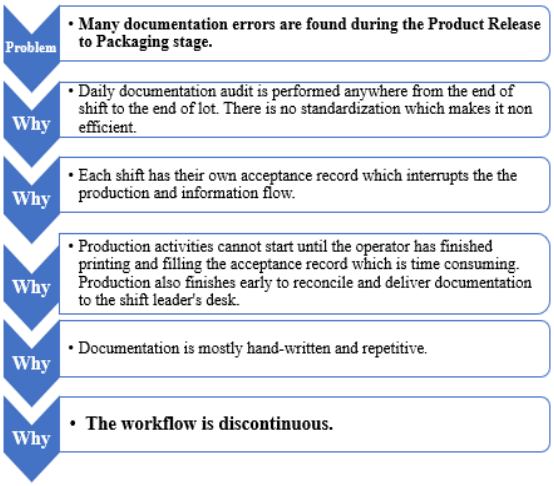


Image 4

Five Why Diagram

Future State- A Proposal

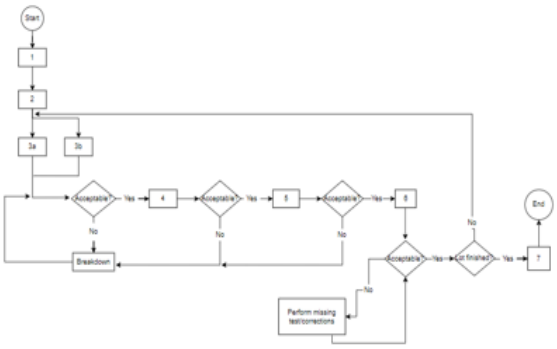
Documentation

To eliminate the interruptions identified on the process, acceptance records will be performed by each lot instead of every shift. Electronic forms were created for each test with their own acceptance criteria and automatic formatting. The conditional formatting was also used to color "pass", "fail", and blank spaces to eliminate the possibility of missing information. The proposed acceptance record includes the Line Clearance and provides space for every shift. It consists of various "realizado" check boxes to reduce the probability of wrong and illegible entries.

Inspections

The first review that was performed by the manufacturing leaders, was replaced with an in-process documentation audit by the same shift quality inspector. Since the tests are only performed at the beginning of each shift, by the second hour an inspector can review documentation for GDP and completeness. After this review, constant monitoring is not necessary later in the process because it will only consist of check marks that can be detected fast by the same operator. The most important benefit of performing the documentation review during the current shift is that any problem detected can be addressed immediately, avoiding affecting the whole shift production.

The Future State Flow Diagram is illustrated on Image 5. After eliminating the wastes and reducing some others, only seven steps are left on the process. Only four steps out of these seven are repeated on the other shifts for a total of 19 steps each lot. This represents the elimination of 24 nonvalue adding activities. Although time is not significant because the shift will always last eight hours, now operators and auditors have more time free to review their own documentation and avoid mistakes.



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.

Image 5

New Workflow Design

Hypothesis Test

A student T distribution was performed to test a hypothesis based on how the new electronic forms will reduce the testing time significantly. First and second shift were used for the data collection. Time of each test and its documentation was measured for ten lots. For the new design, a test run was performed on each machine to measure the time of testing and documenting electronically. Total times are summarized on Table 2.

Table 2

Total Testing Time of Current Handwritten Documentation and New Electronic Forms

First Population		Second Population	
No	Time (min)	No	Time (min)
1	66.86	1	36.00
2	74.98	2	45.35
3	60.93	3	32.83
4	67.86	4	36.00
5	68.07	5	37.51
6	55.30	6	38.24
7	64.82	7	40.70
8	52.58	8	36.01
9	55.66	9	38.85
10	56.99	10	41.09

The null Hypothesis, H_0: $(\mu_1-\mu_2) = 0$ established that there are no differences on the mean of the testing time documenting manually (current process) and the mean of the testing time documenting on electronic forms (new process design). Results are presented on Image 6. The new process demonstrated to reduce the testing time by almost half of the current process. It was also noted from the standard deviation that the variation was reduced because of replacing handwritten forms with electronic forms.

Ho: μ a	EQUALS TO	μ b	
Select one 1 = YES	MORE THAN 1	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)
Miu	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	
Miu A is more than Miu B		

Image 6

Hypothesis Test Results

Since the P-value is less than alpha, the null hypothesis is rejected: the mean of the current process is higher than the mean of the new design.

CONCLUSIONS

An improvement opportunity was identified in Product Release to packaging. Documentation errors were found constantly on acceptance records, a situation that was creating a bottleneck in the process. At product release, the quality inspector reviews acceptance records from every shift once the sub-assembly process has finished. Packaging activities cannot start until the inspector approves the subassembly and releases the quantity produced to unrestricted. A single error found on the records implies a correction that would delay the approval process, and consequently, the packaging and shipping processes.

In the past, the manufacturing and quality departments have worked intensely on enforcing Good Documentation Practices among employees. The efforts included reducing documentation and sampling frequency, constant training initiatives, and the addition of documentation review steps. None of these changes demonstrated successful result. At the same time, it was noted that all improvements were focused on the quality aspects of the process, ignoring the impact of the manufacturing process to the final output. This research analyzed every aspect of the process from documentation to workflow, two of the causes identified preliminary by the Tree Diagram (Image 3).

The documentation is mainly paper based, which is prone to errors related to manual entries and calculations. Most of the errors found were related to illegible entries and omitting information such as signatures and dates. A Five Why analysis (Image 4) led to determine that these errors are due to rushing the documentation process at the start and end of shift. It was observed on the Flow Diagram (Image 2) that the production cannot start until the machine operator prints and fills documentation and performs start-up testing. In addition, the in-process auditor must wait for these tests to be able to start their own testing. The documentation process is rushed to start production, leading to errors. At the end of shift, the reconciliation process is also rushed to be able to take documents to the manufacturing leader's desk on time. These observations led to the conclusion that the root cause of the documentation errors is the discontinuous nature of the process. The issuance of an acceptance record for each shift is interrupting the process and production constantly.

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. The new record consists of checkboxes to mark once the tests has been performed, by whom and when (shift). 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 (see Image 5). The proposed project effectively eliminates 24 activities that were disrupting the flow of value. A student's T distribution was performed to test a hypothesis and demonstrate that the testing time of both processes is in fact different. It was statistically confirmed that the testing time mean of the current manual process is significantly higher that the testing time documenting on electronic forms.

At the packaging area, acceptance records are also performed by each shift. Future projects should include an analysis of the area to implement the same system. This could dramatically reduce the unnecessary copies and reducing the final DHR size. As per regulations, records must be retained for at least ten years, reducing the size of the DHR files provide more space on archives and reduce the costs associated to external storage services. Every other production area that follows the same process should also implement the new design. Benefits include reducing documentation errors, wastes elimination and optimization of the process by allowing production activities to run continuously. This project can potentially cut more than $60,000 from operational costs by reducing the employees needed in the area. Three in-process auditors with overlapping schedules to support the inspections at the start of shift are enough to perform. The current process uses six auditors (two per shift) at a rate of approximately $12 an hour.

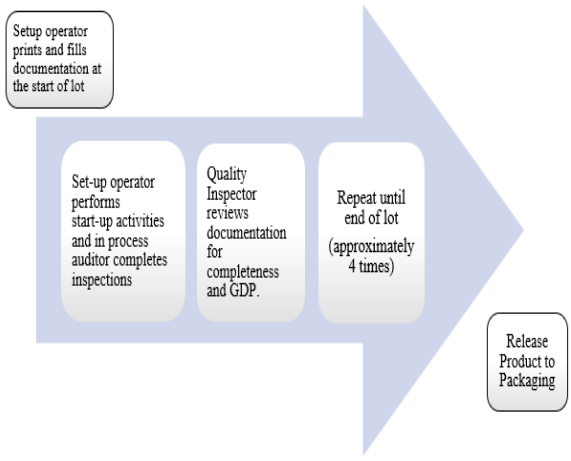


Image 7

Sequence of Steps of the New Design

An important contribution of this work is preparing documentation and employees to facilitate the transition process for a future implementation of electronic batch records.

One of the constraints of the project is that implementing this design will require a change in the manufacturing room layout. Most of the equipment to perform the tests are scattered throughout the area. Another constrain is the complex process of data cycle, creating, changing, and obsoleting documentation. Five new forms will be created, and eight procedures will be changed, a process that can be time consuming, in addition to the many trainings required.

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