

CCL Label Puerto Rico process controls to maintain quality standards for high demanding pharmaceutical customer

Joe Michael Rivera Rosario
Master in Engineering Management
Prof. Héctor J. Cruzado, PhD
Graduate School
Polytechnic University of Puerto Rico

Abstract — Internal and external rejects are one of the common causes for a company to produce waste and therefore increase losses. Serving pharmaceutical clients requires the highest standards to produce quality and acceptable products. The process, in which a label for a big client is produced, was analyzed, and studied. It was determined that study showed the root cause was attached to outdated standard operating procedures and poor preventive maintenance works. It was found that, by updating and modifying the current standard operating procedures both for operators and maintenance team, the output of non-conforming products coming from the equipment can be eliminated, forecasting a \$900,000 loss prevention for 2023. Aligned maintenance team and operators reduced downtime by 68.7% by following correct preventive maintenance procedures to the last detail.

Key Terms — flexible die, flexography, footage, pull tab

INTRODUCTION

CCL Industries is the leading company for packaging solutions worldwide, being the largest label company in the world serving all markets from personal care up to automotive needs. CCL Label Puerto Rico is in Sabana Grande and focuses on two main areas, flexography, and literature, for which 90% of the customers are pharmaceutical companies. Literature machines produce the paper instructions commonly found inside medicine packages. The flexography machine's department, on which the project is directed, focuses on producing labels for medicine containers for products such as Advil, Panadol, and others.

This project is aimed at one of the top portfolios of CCL Label clients, whose monthly

demand is among the largest, ranging from 7 to 10 million units. Non-conforming label has reached losses of \$150,000 from January to February 2023. A non-conforming label is considered one that does not meet the client's quality standards or specifications. The label produced for this client is used on medical containers/serums. What makes it special is that it contains a pull tab, a portion of the label that comes off which contains critical information. Figure 1 shows the construction of label.



Figure 1
Label Pull Tab

The label's pull tab is detaching constantly in the facility and reaching the client when not detected in the inspection process. The objective of this project is to minimize or eliminate this occurrence which will lead to cost prevention and maximize maintenance works to minimize downtime and improve output of good labels.

LITERATURE REVIEW

Flexo printing is a common method used in today's production needs when it comes to printing different varieties of labels at high speeds and volumes [1]. Flexo printing, which is the process used for the client's label, is having different stations that contain an impression plate on where it contains the different impressions of the label. Printing happens by having those impression plates spin in place absorbing ink from the ink tray and as the paper passes through it will create an image/impression. Like any other process or equipment, it has many moving pieces and variables to consider. Die cutting label is difficult and demands high attention by the operator to make sure he's not overcutting and affecting the structure [2]. ~~DMAIC methodology fits perfectly when working with such situations and project improvement projects. The analyze portion help narrowed down the main points to work on which were method, equipment, and man. Having those portions narrowed the project quickly assessed the situation with the standard operating procedures. Since SOP gives the "how to" to operators it was clear the necessity to have them updated to allow proper function and maintenance of the flexo press [3]. Updating this covered most of the project's goals since all pointed out improper procedures. The aspect of having man in the analyze phase is mainly because everyone received training on new implementations. Pointing at equipment guided the project to cover the aspect on preventive maintenance on which were cover on SOP changes and follow up by the maintenance supervisor.~~

METHODOLOGY

A DMAIC problem-solving approach was utilized since it drove Lean Six Sigma critical thinking. The approach effectively resolved the current situation with its five phases: Define, Measure, Analyze, Improve, Control.

Define

The project charter was the main tool used to present the scope of the project. Different areas and personnel participated in where the discussion of the objectives and goal was the main topic. The tool for this was voice of customer (VOC), which is a basic tool to get feedback from person to person. Every operator and personnel presented information they had.

Measure

The current process was visited and evaluated for data gathering. The first step was determining the totals losses year to date and production output. This was already done by QA and was the reason the project was begun. Losses came to a total of \$150,000 with a production output range of 7-10 million units (labels) per month. The first area visited was the flexible die station on the press. The flexible die is the component that performs the perforation/cut of the label. Please refer to Figures 2 and 3 to observe a flexible die sheet and station.

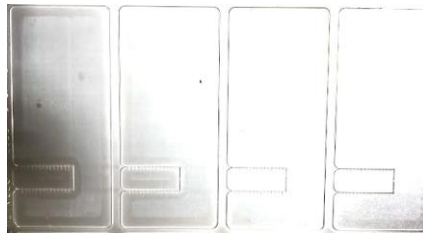


Figure 2
Flexible Die

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Figure 3
Flexible Die Station

Since this piece is changed by operators from time to time, it was found there was not an initial guideline or study of the run life of the flexible dies. These were changed by operator's judgement and SOP mentioned it must be changed every 4 months. This period was assigned aleatory with no data gathering study. A logbook was located near the press where operators recorded each time they changed the flexible die. The logbook was utilized to calculate the data discussed in the analyze phase. Autonomous maintenance procedures were not in place in the operator's work instructions (WI) and preventive maintenance (PM) procedures were signed and "performed" by mechanics but not supervised. This was seen in the work order logbook presenting that specific equipment was the second highest machine with 20 tickets in the period of January to February for the flexo department. The first on the list is an old machine with plans of being decommissioned.

Analyze

The analyze phase was alimented from the measure phase. The first step was calculating the

run life for the different types of dies used for the current product using the logbook of the operators. The reference numbers for the current flexible dies are 00969 and 1008. The run life in days before performing a change is 46 and 66 respectively. This can be observed in Figure 46.

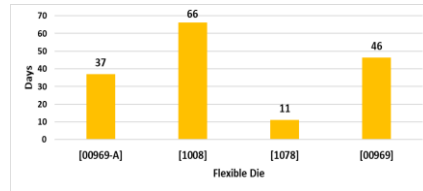


Figure 46
Average Run Life Before Change (Days)

For reference, run life in footage was calculated for flexible dies numbers 00969 and 1008. The average footage obtained was over 1.7 and 5.3 million, respectively. This can be observed in Figure 57.

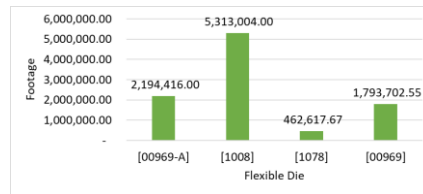


Figure 57
Average Footage Per Flexible Die

The mean time between failures was calculated, which justified the additional responsibilities of the operators in terms of autonomous maintenance and the importance of the supervisor auditing his team's maintenance works. The data used can be observed in Table 1.

Table 1
Work Order Information

Asset	# of Tickets January-February	Total Downtime (Min)	Total Downtime (hr)	Mean Time Between Failure (hrs)
FP2 Arsoma Press	10	920	15.3	30.47

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For the mean time between failures, a 320-hour operating period was used assuming a 40 Hr/Week run time of the press for two months (January & February). The data was inputted into equation of mean time between failures (MTBF):

$$MTBF = \# \text{ operational hours} \div \# \text{ of failures} \quad (1)$$

A total of 30.47 hours was obtained. This value was utilized and presented to justify the importance and relevance of maintenance works because, in theory, the press will fail every 30.47 hours.

Improve

Results from the analyze phase were used as input for the Improve phase. The first step was done by updating the operator's work instructions and standard operating procedures. When performing the flexible die change or every after 15,000 lineal feet, whichever happens first, the operator must clean the flexible die to prevent build during the run. The standard operating procedure was updated with the correct run life of the flexible dies before performing a change, both in footage and days as calculated in the Analyze phase. The maintenance supervisor must perform proper supervision of the maintenance team when doing PM works. Operator and maintenance team orientation and training took place when data and recommendations were presented.

Control

The project was audited correctly, and all changes were approved accordingly by the affected departments. Even though the project has come to full cycle, the standard operating procedures and work instructions will be revisited every six months, per company policies.

RESULTS

The objective was achieved by properly changing SOP and WI as intended from the beginning. Having this done gave the operator and the Flexo department a guide on how the current process should be supervised and maintained to keep good production. The QA department feels

more confident at the time of inspecting the labels. The General Manager is in line with the cost savings since the production will have less waste, which in this case will be non-conforming material before leaving the building. This is backed up by having no rejections by the client up to this date after implementation is performed. The maintenance supervisor has his team aligned with proper PM works for the Flexo press.

Job ticket count went down to a total of 3 job tickets from the period of April to May, a 70% reduction. Total downtime extracted from the maintenance system shows a total of 288 minutes, a 68.7% reduction.

Major findings came from the initial response by the team. Project prevented a tentative \$900,000 loss for 2023 if the rejected maintained its pattern. The team was very proactive after data was presented which increased the desire to help improve.

Too many gaps were found in terms of improper SOPS. This brought up the concern that, at plant level, all SOPS and WI need to be properly reviewed.

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