

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

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. It was determined that the root cause was attached to outdate standard operating procedures and poor preventive maintenance. It was found that, by updating and modifying the current standard operating procedures both for operators and maintenance team, the output of nonconforming 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.

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. 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.

Problem

A 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.

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Methodology

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	
• The project charter was the main tool used to present the scope	
of the project.	
 Different areas and personnel participated in the discussion of 	
the objectives and goals.	
 The tool for this was voice of customer (VOC). 	
Measure	
Losses came to a total of \$150,000 with a production output	
range of 7-10 million units (labels) per month.	
 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. [1]	
Please refer to Figures 2 and 3 to observe a flexible die sheet	
and station.	
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Figure 2 **Flexible Die**

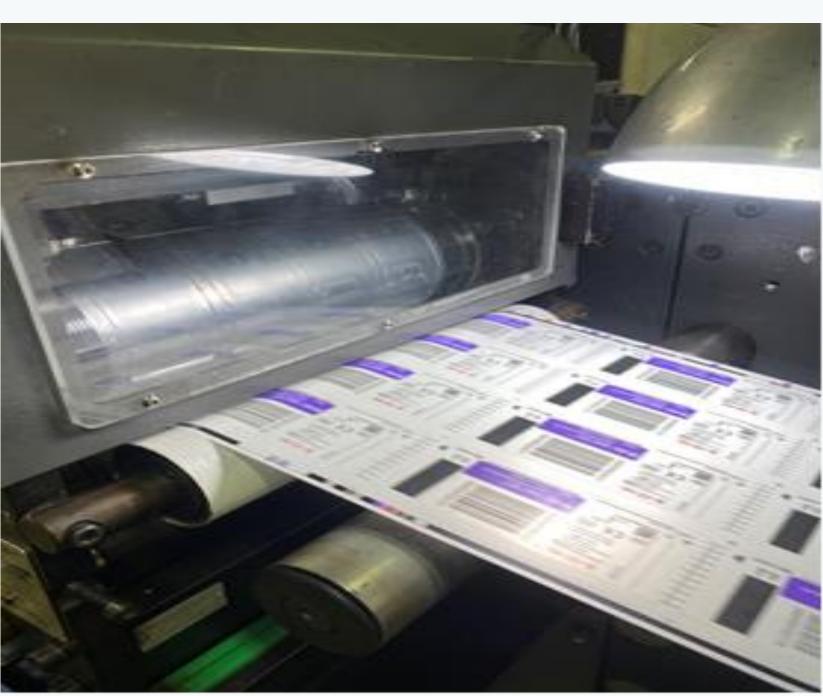


Figure 3 **Flexible Die Station**

- 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.

The mean time between failures was calculated, which justified autonomous maintenance and the importance of maintenance works. The data used can be observed in Table 1.

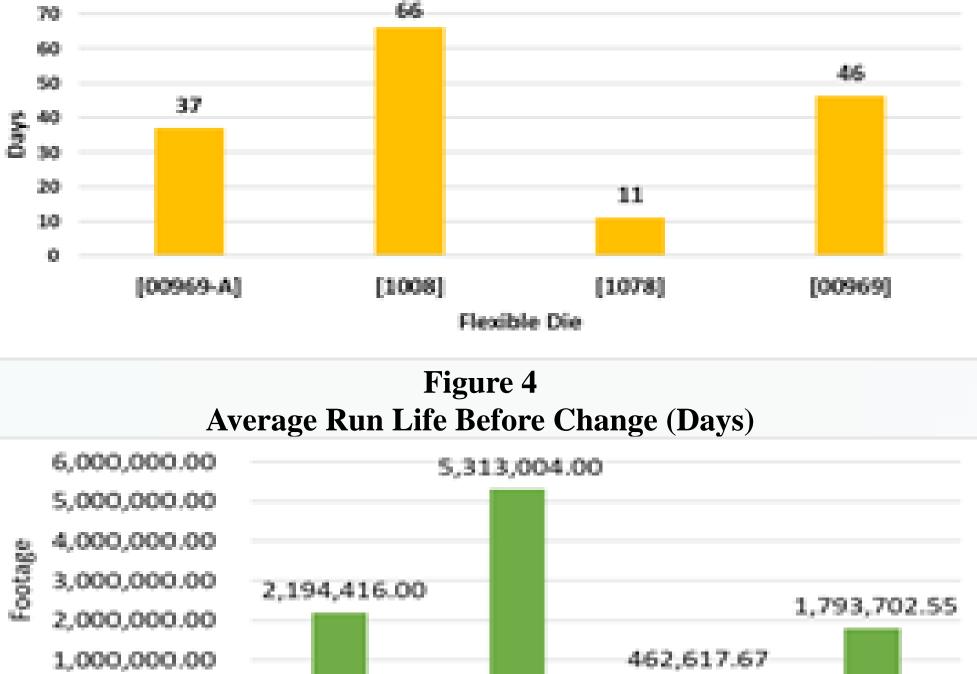
 Autonomous maintenance procedures were not in place in the operator's work instructions (WI).

• Preventive maintenance (PM) procedures were signed and "performed" by mechanics but not supervised.

• Work order log presented the press was the second highest failing machine with 20 tickets from January to February. 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. This can be observed in Figure 4 and figure 5.





[00969-A]

[1008]

[1078]

Flexible Die

[00969]

Average Footage Per Flexible Die

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

A 320-hour operating period was used assuming a 40 Hr/Week run time of the press for two months (January & February).

MTBF = # operational hours + # of failures (1)

Improve

- Updated operator's work instructions.
- Clean flexible die station to prevent particulates from building up every 15k lineal feet or when performing a change.
- Standard operating procedure was updated with the correct run life of flexible dies.
- Operator and maintenance team orientation and training took place to present the recommendations.

Control

- Project was audited correctly, and all changes were approved.
- Process will be revisited every 6 months per company policy.

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.

Future works involve revising sop use for critical clients in CCL's portfolio to create the correct plan of action in a preventive way thinking and not reactive.



Results and Discussion

• 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.

Project prevented a tentative \$900,000 loss for 2023 if the rejected maintained its pattern.

Updated SOP and WI for operators and maintenance team.

• Less waste, which in this case will be non-conforming material.

No rejections related to pull-tab year to date.

Conclusions

Future Work

Acknowledgements

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Together, their collective efforts and unwavering dedication have played a vital role in the shaping of this project.

References

[1] "New solutions for die-cutting challenges," FlexoTech, https://www.flexotechmag.com/key-articles/20506/newsolutions-for-die-cutting-challenges/.