Improving the Overall Equipment Effectiveness of a Hemostatic Products Production Line in a Medical Devices Company

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Abstract

Overall Equipment Effectiveness (OEE) is a performance indicator highly used in the Medical Devices industry. By analyzing the results of this indicator, the organization can reduce losses in the manufacturing process and increase productivity. Due to a demand increase of hemostatic products in a medical device company, a productivity and efficiency increase of 5% in Line C is needed. The Multivac Packager was identified as the bottleneck step in the manufacturing process of the hemostatic products. This project aims to determine the baseline OEE value for this equipment and identify the root cause of the most influential losses. The calculated OEE for the Multivac Packager of 27% is under the standard world-class of 85-90%. Results show that the components of Availability and Performance should be improved to increase the productivity and efficiency of Line C. There were three very influential losses that were identified: operator lunchbreak, changeover, and setup processes.

Introduction

Overall, higher productivity and efficiency translate to a more productive organization. Every year the manufacturing organizations receive the forecasted demand for the next year. Based on the received forecast, adjustments in production are made to ensure the fulfillment of demand without increasing costs.

This project arises as an initiative in a medical device company that manufactures hemostatic products that is facing a demand increase from 1.2 million units in 2021 to 1.3 million units for 2022. The OEE it is a performance indicator highly used in the industry to understand current performance and identify opportunities to increase efficiency and productivity. By identifying the Line C bottleneck and calculating the OEE, is intended to identify actions to achieve a 5% of OEE improvement.

Figure 1 Hemostatic Product Kit Box

Objective

Improve the OEE of Line C by at least 5%.

Methodology

The first step of this project consisted of evaluating Line C manufacturing operations to identify the bottleneck. Figure 2 shows the Line C manufacturing operations. Pouching and Packaging operations were identified as the bottleneck process observation, capacity, and output analysis. Therefore, the focus of this project is on the Multivac Packager, equipment used in the packaging, and pouching operations.

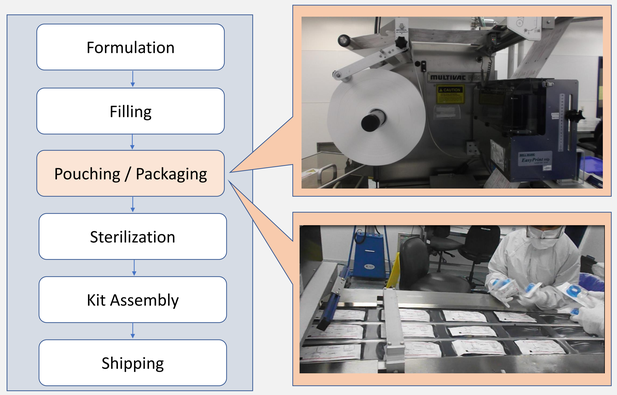


Figure 2 Line C Manufacturing Operations

In the second phase, the data collection tool was implemented to support the generation of the results regarding the OEE of the Multivac Packager, through the collection of events of unavailability records, production output, and results of quality inspections. The collected data was analyzed with a cross-functional team to validate data correctness. Figure 3 shows an example of the data collection tools.

Multivac Report

Date:
Initial: Lot #:

Pouching Time		Minutes Multivac running and producting pouches
Break 1		Minutes from stop to restart of production
Lunch/Dinner		Minutes from stop to restart of production
Break 2		Minutes from stop to restart of production
Meetings		Minutes for team meetings, fire drills, etc during shift
Training		Minutes for team training during shift
Shift Change		Minutes this shift not producing for shift change. Includes gown times at start and end of shift.
Set Up		Minutes to set up multivac. Includes Burst test time
Clean Up		Minutes to clean up at end of production
Die Changeover		Minutes to change over dies
Broken Machine		Minutes lost to machine breaking down Cause(s):
Other Downtime		Minutes lost for other causes
Production Idle		Minutes waiting for missing inputs or materials
Production Idle		Minutes idle due to online quality issues
Rework Time		Minutes to rework pouches and insert pieces from reworked pouches
Unscheduled Time		Minutes Shift not scheduled to produce pouches
Other		Minutes for other reasons Describe:

Downtime Reason	week 1	week 2	week 3	week 4	week 5	week 6
Break 1	435	465	375	450	525	135
Lunch/Dinner	1020	1110	930	1050	1305	285
Break 2	225	375	180	300	270	120
Meetings	200	230	215	235	250	80
Training	45	130	165	70	20	0
Gowning	1000	1115	830	910	1145	305
Shift Change	430	410	355	135	280	75
Set Up	1061	1329	905	1145	1342	445
Signatures/Release	129	95	40	210	95	10
Clean Up/Reconciliation	935	860	915	894	1087	318
Monthly Cleaning	35	55	60	40	30	0
Die Changeover	705	705	545	555	965	297
Rotation to Filling	75	300	0	45	425	120
Waiting for Inputs	80	195	0	90	215	105
Quality Issues	0	20	0	11	60	30
Broken Machine	460	292	130	329	395	0
Other Downtime	4376	1732	1010	1173	504	179
Finger Gripping	327	940	340	397	685	255
Rework Time	335	355	290	265	302	110

Figure 3 Data Collection Example

Once data was validated, the Multivac Packager OEE baseline, the availability ratio (AR), performance efficiency (PE), and the quality rate (QR) were calculated. The following equations were used for the calculations.

$$OEE = AR \; x \; PR \; x \; QR$$

$$AR\ (\%) = \frac{Run\ Time}{Planned\ Production\ Time} * 100$$

$$PR\ (\%) = \frac{Net\ Run\ Time}{Run\ Time} = \frac{Ideal\ Cycle\ Time\ x\ Total\ Count}{Run\ Time} * 100$$

$$QR\ (\%) = \frac{Good\ Count}{Total\ Count} * 100$$

The third phase consisted of the proposition of improvement actions and their application. The priorities were defined by the criteria of simplicity, required resources, and expected results.

Results

The overall equipment effectiveness is 27%, where the availability of the equipment was 51% of the production time and the performance was 55% while the quality factor is 94%. Table 1 shows the comparison of the equipment indicator and the world-class standards.

Table 1
Comparison between Multivac Packager Machine and World-Class Standards [1]

	Multivac OEE	World-Class OEE
Availability	51%	90%
Performance	55%	95%
Quality	94%	99%

From Figure 3 it can be observed that the biggest losses were related to the time exceeded of lunch/breaks, changeover, and setup.

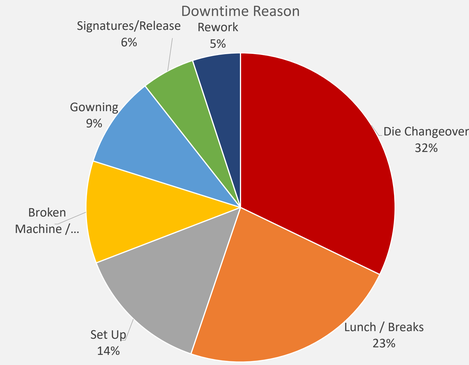
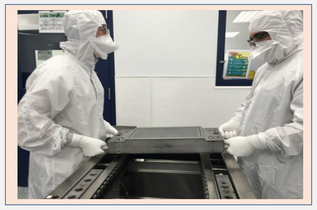
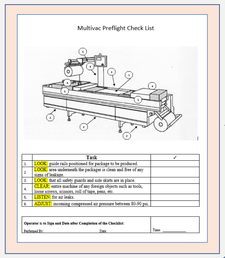


Figure 3 Multivac Packager Downtime Results

As part of the root cause assessment conducted to reduce the big losses, the following actions were implemented:

- Update training material for changeover and setup processes to ensure robustness and completeness.
- Training sessions for changeover and setup processes scheduling a highly skilled operator with a less skilled operator to ensure knowledge and experience are used during training sessions.
- Checklist for the setup process to provide the operator a readiness document before starting a new configuration.
- Update preventive maintenance job plans to ensure it contemplates cutter blade replacement frequency.





Conclusions

The OEE is an indicator that allows the organization to know where they are and helps them to identify where the opportunities are and how to improve them [2]. By calculating the OEE and analyzing each of its components, losses were identified throughout the pouching and packaging manufacturing process of Line C. The Multivac Packager was identified as the bottleneck of the manufacturing process. Most of the losses were related to the time exceeded of lunch/breaks, changeover, and setup. From Figure 4 an improvement of 5% can be observed after implementing the actions identified in this project.

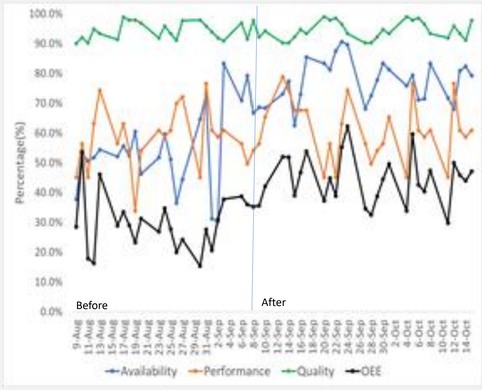


Figure 4 Multivac Packager OEE Results (Before & After Improvement Actions)

Future Work

As part of this project, it is recommended to:

- Integrate the Multivac Packager machine in the TPM program
- Enhance the Maintenance program and Maximo system utilization to track equipment malfunctions, breakdowns, and the downtime.
- Implement a system with downtime barcodes and visual for OEE results in Line C

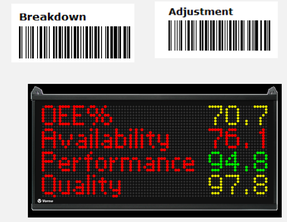


Figure 5 Recommended Tools

References

[1] Gavriluță, A., "A REVIEW OF OVERALL EQUIPMENT EFFECTIVENESS", *TEHNOMUS*, (2017), 112-116.

[2] Dunn, T. "OEE Effectiveness In Manufacturing Flexible Packaging", *Elsevier*, (2015), 77–85.