Sterilizer Temporal Service Shutdown Project

Nicole Tapia
Master in Engineering Management
Dr. Héctor J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract *— Sole sourced sterilization company announced a one-year shutdown affecting adjustable valves manufacturer. The identified root cause was the sole sourcing strategy action taken by a medical device manufacturer that is already experienced on required sterilization ETO technique for adjustable valves. The manufacturing process of adjustable valves, as well as inventory levels and future requirements, were studied to understand current situation and possible solutions. It was found that by relinquishing inhouse sterilization sutures capacity to sterilize adjustable valves, not only ensured business continuity but also was a costs and lead time saving opportunity.*

Key Terms *— Backorder, Lead Time, Overstock, Process Flow*

INTRODUCTION

An American multinational medical device manufacturer company is committed to their public by delivering high quality, state-of-the-art built products, extending patients life worldwide. Their most renowned manufacturing division located on the Dominican Republic, CST (Cerebrospinal Technologies), produces adjustable valves, an innovative therapy to treat hydrocephalus with the ability to adjust pressure levels without the need of performing surgery as conventional valves require. Moreover, the Dominican Republic facilities are conformed by four divisions: Building 1 - Sutures, Building 2 – Endo mechanical devices, Building 3 –Laboratory services and sutures sterilization, and Building 4 – CST.

To ensure the delivery of patient safe adjustable valves, the medical device manufacturer relied on a sole sterilization company located on the United States, outside the Dominican Republic. The medical device manufacturer was informed that sterilization company will shut down for 1 calendar year, starting January 2024. Since sterilization was sole sourced, market availability, backorders metrics, perishable raw material, personnel, and market share were threatened by the temporal service shutdown of the sterilizer.

The medical device manufacturer intends to continue to operate during the sterilizer temporary shutdown. Therefore, the following objectives were established:

- Ensure sterilization of at least 65% of product demand in the calendar year 2024.
- Maintain inventory levels with a maximum overstock monthly allowance of 10%.
- Implement a solution that will keep sterilization cost equal or lower than actual cost.
- Reduce costs of operations that will compensate for a higher sterilization cost than current.

LITERATURE REVIEW

Adjustable valves to treat hydrocephalus require proper sterilization techniques, inventory management and adequate forecasting are crucial to maintain lead times that ensure delivery to market.

Required Sterilization Technique

Adjustable hydrocephalus valves, part of the shunt system, contain a wide variety of materials. The mechanism that makes possible its novelty adjustable function contains materials like silicone, metal, magnet, ruby, and polypropylene. Ethylene oxide is the most used technique for sterilizing this type of product. Usually packaged in a double pouch, ethylene oxide will effectively reach the product without damaging or affecting the many materials composition properties. FDA has consensus standards that keep ethylene oxide levels

within safe ranges, since its emissions are known to be carcinogen [1].

Inventory Management and Forecasting

The inventory management situation of product must be planned out carefully. What was forecasted must come close to the reality avoiding the two main issues at inventory management level: the stockout and overstock [2]. Stockout in warehouses require companies to manage dynamically their suppliers, establishing multiple supplier relationships to provide one raw material eliminates the dependance on one sole supplier, and in addition it can provide cost saving opportunities through these suppliers relations [3]. On the other hand, overstock might assure the safety of always being able to deliver to clients, or manage with ease an unexpected increase in demand, however it is not cost effective, overstocking costs money in inventory levels, warehouse employees to keep that inventory and costs of losing perishable product.

The min – max deterministic method to control inventory is proven to be ineffective, since demand and market move in a probabilistic way, integrating with simulation tools like Monte Carlo simulation can be used to introduce the randomness nature of demand [2]. If not careful, overstock situations can turn into backorder, an apology and promise to customers that once back available in stock, the item will be delivered to them [4].

METHODOLOGY

Scope and Current State Measurement

Medical device manufacturer delivers their adjustable valves for hydrocephalus treatment following the diagram shown on Figure 1. As a manufacturer practice, shipments of valves to sterilizer were performed once there is one week of valves production in existence (approximately 1,378 EA). Summarizing the total lead time to arrival to distribution center to 3.25 weeks.

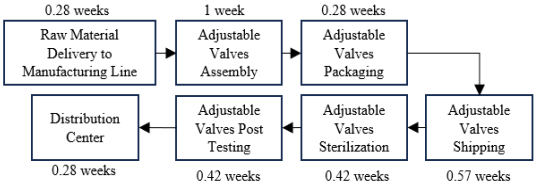

Figure 1
Adjustable Valves Delivery Flow Chart

Table 1 shows the distribution center inventory metrics at the end of September 2023. The medical device manufacturer had an overstock of 18% for September 2023, 8% above company policy. Overstock happens mostly due to performance fluctuations of the manufacturing line that assembles the adjustable valves. Performance estimations were calculated assuming a quality portion or yield of 60%. However, as evidenced on Figure 2, variations above 60% of yield have occurred, creating overstock of inventory above safety allowance.

Table 1
Inventory Metrics Distribution Center, September 2023

Metric	Result
Available Inventory	9,233 EA
Ordered Units	7,200 EA
Service Level	100%
End to End Lead Time	3.67 weeks
Safety Stock Policy	10%
Overstock	18%

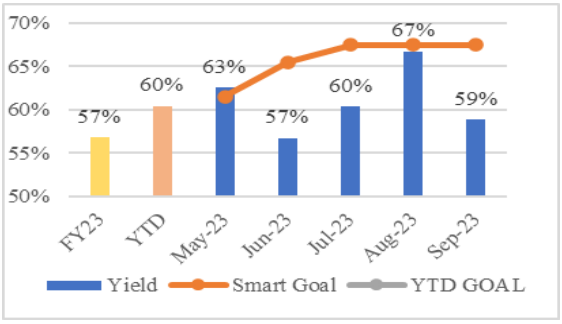

Figure 2
Adjustable Valves Manufacturing Yield

In addition, time study analysis was conducted, Figure 3 demonstrates the large OPE loss of the

production of hydrocephalus valves (48%), almost half of productive time is loss. With an expected yield of 60%, takt time for 1 unit is 204 secs while cycle time is 210 secs, there is no margin for coverage where any eventuality happens during manufacturing process.

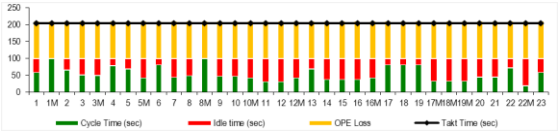

Figure 3
Adjustable Valves Line Balancing Graph

The Scope of this project to achieve defined objectives was the adjustable valves manufacturing line located on Building 4 of the medical device manufacturer on Dominican Republic.

Demand Plan Forecast and Inventory Requirements

Demand historic data with identified trends were extracted from SAP ERP System, applied with the Min-Max method, Table 2 demonstrates the results forecasted.

Table 2
Adjustable Valves Forecast and Inventory Requirements 2023 - 2024

Period	Forecasted Requirement
October 2023	8,670
November 2023	5,720
December 2023	6,700
January 2024	2,100
February 2024	1,500
March 2024	2,430
April 2024	4,910
May 2024	4,820
June 2024	4,310
July 2024	4,420
August 2024	4,090
September 2024	2,270
October 2024	2,840
November 2024	1,770
December 2024	550

Adjustable valves market is compound by 30% US and 70% outside US. Table 2 forecasted requirement was split into market percentage to project future backorder, Figure 4 demonstrates the results of projections, where if nothing was implemented related the temporal shutdown of the sterilization company, backorder would have scaled to 1.78M for outside of US market and 0.76 M of US market, reaching a total of 2.54 M by the end of calendar year 2024.

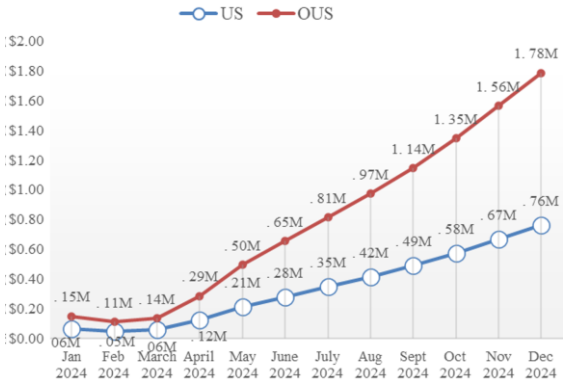

Figure 4
Adjustable Valves Market's Backorder Projection

Proposed Solutions and Economic Evaluations

Brainstorming session was held with assigned multidisciplinary team, resulting nominated the following proposed solutions:

- S1-Manufacturing capacity increase: Produce 65% of calendar year 2024 demand by increasing assembly line capacity.
- S2-Inhouse sterilization: Use Building 3 (Laboratory services and sutures sterilization), already experienced on ETO sterilization, for sutures product, sacrificing sterilization of 30% volume of absorbable suture.
- S3-Subcontract sterilization company.

Quotes were received from various suppliers to estimate costs for the economic evaluation of proposed solutions, Table 3 exhibits cost benefit analysis for each proposed solution, the most economical solution with the highest cost/benefit ratio was S3 subcontract sterilization company, followed by S1 to increase manufacturing capacity, and finally S2 Inhouse sterilization. All three alternatives presented a benefit cost ratio above 1 signifying no losses to the medical device manufacturer.

Table 3
Economic Evaluation of Proposed Solutions

	S1	S2	S3
Equipment	$1,000,000	-	-
Fixtures	$15,000	$ 4,000	-
Manufacturing expenses	$ 3,000	$ 5,160	-
Cost of Sterilization	$204,500.0	-	$318,283.8
Cost of Overstock	$ 576,822.4	$ 295,222.2	-
Cost of opportunity	-	$ 2,000,000	-
Validation Costs	$100,000	$ 386,280	$ 502,648
Total Costs	$1,899,322	$2,690,662	$820,931.8
Benefits (sold units)	$8,900,535	$9,018,223	$7,922,084
C/B Ratio	4.68	3.35	9.65

Solution Selection

The Analysis Hierarchy Process matrix was used to decide the solution implemented to mitigate the impact of the sterilizer temporal shutdown. A meeting held with management determined the following constraints in conjunction with economic evaluation results to select the implemented solution:

- Economic Evaluation (EE)
- Implementation Lead Time (ILT): Selected solution must be implemented under 4 months (time before sterilizer temporal shut down occurs).
- Overstock Levels (OL): Table 1 presented an overstock of 18%, management did not want to incur on any solution that would wound the already missed metric.
- Transportation Lead Time (TLT): Management orders were to not affect lead time, only solution that maintain either improved it were selected.

Weights for each constraint were assigned. Table 4 presents the matrix for each constraint, followed by Table 5 exhibiting the normalized weights and results for the pairwise matrix. Based on the results, S2 (Inhouse sterilization) was selected with an overall score of 0.3961. Management approved the implementation of this solution despite having to sacrifice 30% sutures product sterilization, its implementation reduced lead time of product delivery to clients and cost savings in shipping and utilizing inhouse ETO sterilizer.

Table 4
Initial Weights of Constraints for Comparison Matrix

	ILT	EE	OL	TLT	Weights
ILT	1	5	2	4	0.5115
EE	0.2	1	0.5	0.5	0.0986
OL	0.5	2	1	2	0.2433
TLT	0.25	2	0.5	1	0.1466

Table 5
Normalized Comparison Matrix and Overall Score

	S1	S2	S3	Weights
ILT	0.571	0.286	0.143	0.5115
EE	0.159	0.252	0.589	0.0986
OL	0.088	0.669	0.243	0.2433
TLT	0.069	0.426	0.506	0.1466
Overall score	0.3395	0.3961	0.2644	

Process Validation and Implementation

Change control process was followed through to validate the use of local sterilization Building 3 to sterilize adjustable valves. The following activities were completed successfully without deviations:

- APQP Revision.
- Master Validation Plan.
- Operational qualification sterilization oven.
- Fixture validation, post sterilization adjustable testing.
- Performance qualification.
- Bacterial Endotoxin, Microbiology & pyrogen test.
- Work instruction changes.
- Master Validation Report.
- Risk Assessment.
- Change Control closure.

Objectives Check for Valves Therapy Delivery Continuity

Medical device manufacturer produces with its challenged OPE as presented on Figure 3 and quality percentage of 60%, a manufacturing output of 1,378 EA weekly, monthly 5,512 EA. Table 2 exhibits highest forecasted monthly requirement for calendar year 2024 is 4,910 EA, with current time study manufacturing and in-house sterilization capacity, manufacturer ensures sterilization for 100% of product demand of calendar year 2024.

Overstock did not happen due to utilization of the inhouse sterilizer, since lead time was reduced and medical device manufacturer no longer must accumulate 1 week's inventory prior sterilization to ship, overstock levels are projected to reduce.

Figure 1 demonstrated that on average the lead time to deliver 1,378 EA adjustable valves to distribution center was 3.25 weeks, once implemented the use of the local in-house sterilizer building, lead time was reduced to 1.40 weeks. Figure 5 presents the implemented process flow, where significant time reductions due to utilizing in-house sterilizer were achieved.

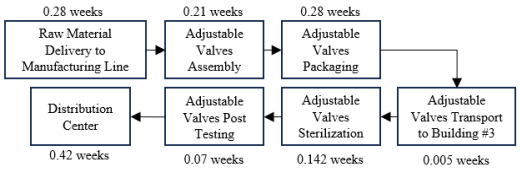

Figure 5
Adjustable Valves Delivery Flow Chart In-House Sterilization

Operations costs were reduced. Only one shipment is being made outside the country directly to the distribution center. Additional cost savings were also found due to the same amount of valves delivery in 43% less time (1.40 instead of 3.25 weeks). As for sterilization cost, Dominican Republic's work force is less expensive than the United States reducing the cost per valve from $184.48 US to $163.52. All project objectives were exceeded.

CONCLUSIONS

Temporal shutdown of sterilizer no longer poses a threat for medical device manufacturer product delivery. Validated inhouse sterilizer served only to benefit the medical device manufacturer and learned lessons regarding sole sourcing, increased lead time and cost.

Inhouse sterilizer is a success regarding the convenience of the reduced lead time, inventory management improved since sterilization happens in a continuous flow, rather than accumulative, sterilization costs were reduced, as well as the medical device manufacturer has more quality control over its product being sterilized inhouse.

REFERENCES

[1] FDA, "FDA," 24 July 2023. [Online]. Available: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.

[2] R. a. A. Khairunisa, "Integration of deterministic and probabilistic inventory methods to optimize the balance between overstock and stockout," IOP , Yogyakarta, 2020.

[3] S. A. S. Islam, "Prediction of probable backorder scenarios in the supply chain using Distributed Random Forest and Gradient Boosting Machine learning techniques.," *Big Data*, 2020.

[4] R. a. C. L. J. Aláez-Aller, "Dynamic supplier management in the automotive industry," *International Journal of Operations & Production Management*, 2010.