Process Improvement and Cost Reduction Opportunities by a Change in the Packaging Material of Human Thrombin Component Coming in Vials

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Abstract

Human Thrombin is a bleeding control agent that is formulated, filled into a glass vial, and lyophilized to maintain stability. In order to be shipped, the vials are packaged in a container made from cardboard material. Particulate matter coming from the packaging is transferred to the vials which results in the addition of a cleaning step prior to subsequent processing. An alternate plastic packaging material consisting of Polyethylene Terephthalate and Polypropylene was evaluated. Assessment of the cleaning process showed that a change in the current packaging represents an improvement in terms of the elimination of a non-value- added step and the associated labor cost. Additional evaluation demonstrates that this change also implies a reduction in scrap and in the costs applied for shipping. By identifying and implementing an alternate packaging material, product quality is improved, and non-value-added process steps and associated costs are eliminated, which will result in costs savings.

Introduction

Hemostatic agents, such as Human Thrombin, are used in surgical applications for bleeding control. This component is formulated and filled into a glass vial and packaged in a cardboard container for shipping. Particulate matter coming from the packaging container is being transferred to the vials. This results in the addition of a non-value-added cleaning step prior to the use of the vials in manufacturing as to reduce the incidence of carboard particles. This step represents an increase in manpower utilization and labor cost.

Background

Human Thrombin is a protein isolated from human plasma that plays a critical role in coagulation. Thrombin in combination with other agents is used in surgical applications to achieve hemostasis. According to Gale [1], “hemostasis is the physiological process that stops bleeding at the site of an injury”. Two Thrombin configurations are manufactured: 5mL and 10 mL. The packaging of this component consists of shipping cases and trays made of cardboard. At the manufacturing site, each vial is loaded along with other components in a pouch, sealed, and inspected for cleanliness. This requirement is established as a pouch free of visible contaminants, including particulate matter. In order to meet the requirement for cleanliness, the Thrombin product is transported to a designated area for cleaning and removal of particulate matter generated from the cardboard packaging. Alternatives are available to substitute the use cardboard material. These include the use of plastic such as Polyethylene Terephthalate (PET) and Polypropylene (PP). According to Guo, et al, [2], PET is widely used in the packaging industry, has a large number of consumption, and high recovery value. On the other hand, PP holds properties such as excellent processability and chemical resistance [3]. Furthermore, Aumnate, et al, [3] states that due to its physical properties such as high strength and rigidity, PP is widely used as packaging material. These characteristics make plastic suitable as a packaging component and proposes an alternative for particle matter reduction coming from cardboard.

Problem

This study seeks to establish an alternate packaging material for Human Thrombin vials to eliminate the generation of particle matter coming from the cardboard current packaging; eliminate the cleaning process step; eliminate the cost associated to the cleaning process; reduce the cost associated to the shipment of vials; and improve product quality.

Methodology

Alternate packaging materials and configuration was assessed along with the Supplier of Human Thrombin. The selected alternative includes two types of plastic material: vial trays made of Polyethylene Terephthalate (PET) and shipper case made of Polypropylene (PP). Figure 1 shows the new plastic packaging prototype.

Figure 1
New Plastic Packaging Prototype

Determination of Cost Savings Opportunities

The cleaning step of the Thrombin vials was evaluated to determine the labor hours applied to the process, the associated cost, along with opportunities for waste reduction. An operator is designated to perform the cleaning on a determined quantity of vials based on production schedule. The labor hours applied were determined for each code; 5 mL and 10 mL. The labor hours applied were multiplied by the labor cost to determine the total cost per month. The results were added to obtain the yearly cost for cleaning. Subsequent assessment was made on scrap data related to Thrombin pouches rejections at the Area for Final Processing due to Particle Matter.

On the other hand, the new packaging provides for a new configuration that allows more vials per case, as presented in Table 1.

Table 1
Vials and Pallet Quantity Comparison between Current and New Packaging Configurations

Code	Current Qty of Vials per Box	New Qty of Vials per Box	Current Qty of Pallets	New Qty of Pallets
5mL	400	560	24	24
10mL	70	180	32	24

Cost savings opportunities were explored from a reduction of the number of pallets used for shipping. As the number of vials per case is increased in the new packaging, a reduction in the number of boxes is represented, which translates to a reduction in the number of pallets. Information was available by the Planning Department on the orders of vials from January to June 2021 for each code. Comparison was made between the number of boxes for the current packaging and the number of boxes for the new packaging. These numbers were used to calculate the number of pallets and the potential cost saving coming from a reduction.

Results and Discussion

Upon assessment of process flow, it is determined that the cleaning step creates material flow interruptions and waste in the form of transportation. Cleaning Step Process flow is presented in Figure 2.

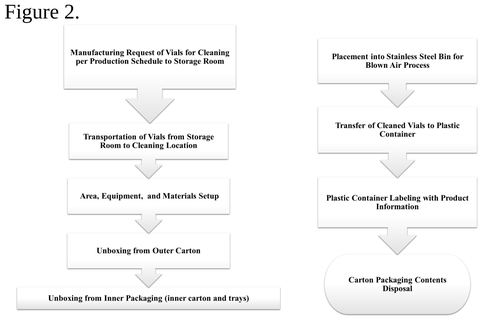

Figure 2
Cleaning Step Process Flow

The Cleaning step has an associated time and cost as presented in Table 2.

Table 2
Time and Labor Cost Applied to Thrombin Vials Cleaning Step

Thrombin Code	Evaluated Quantity (ea)	Average Time for Cleaning (hr)	Labor Cost Applied per Hour
5 mL	2,400	0.67	39.94
10 mL	5,200	4	39.94

This step represents a non-value-added activity and its elimination proposes the removal of the cost associated which, from January 2020 up to Mid-April 2021, is calculated as $25,538.37.

Particulate Matter Reduction

High incidences of rejected pouches at the Area for Final Processing are observed due to Particle Matter. Percent of rejections per Particle classification is presented in Figure 3 and Figure 4. It is expected that this project results in a reduction in the percent of rejections for Thrombin Pouches due to carboard along with the associated cost reduction in scrap.

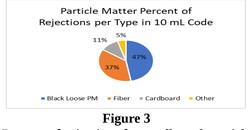

Figure 3
Percent of rejections for cardboard particle matter in 10 mL Code

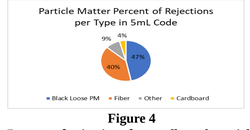

Figure 4
Percent of rejections for cardboard particle matter in 5 mL Code

Cost Savings Coming from Pallet Reduction

Based on the available data on the orders of vials from January to June 2021, it is determined that the new configuration proposes a cost reduction in shipping activities as presented in Table 3 and Table 4, Figure 5, and Figure 6.

Table 3
Box and Pallet Quantity Comparison between Current and New Packaging Configuration and Estimated Price Difference for 5mL Code

Month	Qty of Ordered Vials	Current Qty of Boxes	Estimated Qty of Boxes	Current Qty of Pallets	Estimated Qty of Pallets	Pallet Cost $	Cost Difference $
Jan	60,759	152	108	6	5		2,583.45
Feb	66,936	167	120	7	5		2,846.09
Mar	66,482	166	119	7	5		2,826.79
Apr	44,383	111	79	5	3	$1,428.66	1,887.15
May	49,339	123	88	5	4		2,097.88
Jun	62,170	155	111	6	5		2,643.45

Table 4
Box and Pallet Quantity Comparison between Current and New Packaging Configuration and Estimated Price Difference for 10mL Code

Month	Qty of Ordered Vials	Current Qty of Boxes	Estimated Qty of Boxes	Current Qty of Pallets	Estimated Qty of Pallets	Pallet Cost $	Cost Difference $
Jan	65,788	940	365	29	15		20,202.59
Feb	30,193	431	168	13	7		9,271.86
Mar	49,844	712	277	22	12		15,306.41
Apr	48,045	686	267	21	11	1,428.66	14,753.96
May	46,704	667	259	21	11		14,342.16
Jun	51,135	731	284	23	12		15,702.86

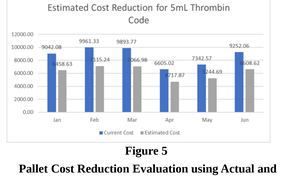

Figure 5
Pallet Cost Reduction Evaluation using Actual and Forecasted Quantities of vials from January to June 2021 for 5mL Thrombin Code

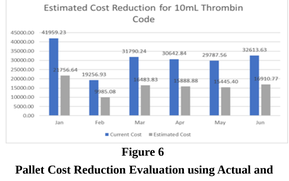

Figure 6
Pallet Cost Reduction Evaluation using Actual and Forecasted Quantities of vials from January to June 2021 for 10mL Thrombin Code

Conclusions

Assessment of the Thrombin vials cleaning shows that a change in the current packaging from cardboard to a new plastic configuration represents an improvement in terms of the elimination of a non-value-added step, along with the elimination of the labor cost applied for the process. Additional evaluation on scrap data for Thrombin pouches rejected due to particulate matter, demonstrates that this change also implies a reduction in the percent of scrap and an associated cost reduction coming from a decrease of cardboard particles. Classification of particles demonstrates that cardboard accounts for an average of 11% of the particles found on rejected pouches for 10 mL codes and for a 4.0% in 5mL Thrombin Pouches Codes.

It is also demonstrated that the new plastic configuration results in a reduction in the costs applied for shipping. This reduction comes from a decrease in the number of pallets, being the volume of this shipping component the determining factor for cost. The available data on the orders of vials from January to June 2021, allowed to demonstrate a cost reduction of approximately 29 % for 5 mL codes and 48% for 10 mL codes.

Future Work

This study is aligned with the Company initiative for Cost reduction. By identifying and implementing an alternate packaging material for the Thrombin vials, product quality will be improved and non-value-added process steps and associated costs are eliminated, which results in costs savings. This study also promotes further areas of research including reduction of defects introduced by the handling of vials during the cleaning process, such as cracks.

Acknowledgements

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References

[1] A.J. Gale, “Current Understanding of Hemostasis”, Toxicologic Pathology, vol. 39, no. 1, 2011. [Online serial]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3126677/. [Accessed Mar 29, 2021].

[2] J.C. Guo, X. Li, Y. Guo, J. Ruan, Q. Qiao, J. Zhang, Y. Bi, F. Li “Research on Flotation Technique of separating PET from plastic packaging wastes”, Procedia Environmental Sciences, vol. 31, 2016. [Online serial]. Available: https://www.sciencedirect.com/science/article/pii/S1878029616000256. [Accessed Apr 09, 2021].

[3] C. Aumnate, N. Rudolph, M. Sarmadi, “Recycling of Polypropylene/Polyethylene Blends: Effect of Chain Structure on the Crystallization Behaviors”, Polymers, vol. 11, no. 9, 2019. [Online serial]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6780393/. [Accessed Apr 09, 2021].