Proposing A Mitigation Plan of The Mda Sticker Labelling Processing Time Using Cause and Effect Analysis

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Abstract

With increasing concerns regarding product quality and safety in the pharmaceutical and healthcare industries, adherence to good manufacturing practices (GMP) and good distribution practices (GDP) guidelines plays a vital role in ensuring the integrity and efficacy of pharmaceutical products throughout the supply chain. Based on (MDA, 2018), the labelling of medical devices meant for human beings, is an important process that needs to be efficient especially in stock staging. For this study, the focus is on mitigating the processing time for the labelling area, before and after staging space, by determining the cause of delay for each type of activity in the process. The descriptive analysis using Pareto analysis and Ishikawa diagram are proposed to mitigate the MDA sticker labelling processing time. While this specificity allows for a detailed exploration within this domain, it may compromise the generalizability of findings to broader contexts within the pharmaceutical or healthcare sectors.

Keywords: Labelling Processing time, Pareto Analysis, Ishikawa diagram, Cause Effect analysis

Introduction

With increasing concerns regarding product quality and safety in the pharmaceutical and healthcare industries, adherence to good manufacturing practices (GMP) and good distribution practices (GDP) guidelines plays a vital role in ensuring the integrity and efficacy of pharmaceutical products throughout the supply chain. Additionally, compliance with Medical Device Authority (MDA) labelling requirements is essential for accurate and comprehensive information dissemination to healthcare professionals and end-users.

Based upon (MDA, 2018), the term of medical device is including any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for several relevant purposes. The efficiency of stock staging, particularly in the context of pre- and post-labelling phases, plays a pivotal role in the timely execution of processes within a given system. The strategic allocation and utilization of space in stock staging areas have a substantial impact on the overall workflow, influencing the potential causes of delays. This study aims to delve into the correlation between stock staging space management and the occurrence of delays, shedding light on the critical nuances that underscore labelling process efficiency in various industries. By examining the layout of space allocation before and after the labelling process, seek to uncover insights that contribute to a more streamlined and time-effective workflow.

Based on Pasandideh et al. (2017), the factor that causes a delay in warehouse space is the limited capacity of the retailer's warehouse to store the products. This limitation is an approximation for the maximum level of inventory at the retailer, and it can lead to delays in storing new products or replenishments, impacting the overall inventory management process. The issue of limited space affecting costs in different operations is a complex challenge that needs observation. As industries try to find the right balance between limited space and financial efficiency, it's crucial to understand the details. Based on (Rebelo et al., 2021; Buba et al., 2019), the warehouse space limitation has a significant impact on the average total cost of optimal conditional proportional-size delivery policies. When the buyer's warehouse capacity is less than the adequate threshold and decreases, the system total cost strictly increases. Based on (Rebelo, et al., 2021; Bylka, 2020; Fumi, et al., 2013), the warehouse faced challenges with saturation and high occupancy rates, reaching 200% in some areas, and an overall bin occupation of 103.06%.

For this study, the aim is to focus on mitigating processing time for the labelling area based on before and after staging space. Therefore, the objective of this study is to determine

the cause of delay for each type of activity in the labelling process. The research exclusively centres on the specific context of MDA labelling types. While this specificity allows for a detailed exploration within this domain, it may compromise the generalizability of findings to broader contexts within the pharmaceutical or healthcare sectors.

For the analysis phase, descriptive and research data analysis were used to obtain concise numerical values of the variables and visually analyse the data using different types of drawings and graphs (Živicnjak, et al., 2022; Rebelo, et al., 2021). The study utilized a class-based storage technique and volume analysis to suggest changes such as adding new bins, redesigning existing bins, and acquiring Cantilever beams. These changes could lead to a 9.77% increase in capacity and significant cost savings (Rebelo, et al., 2021).

The research by Jum'a and Basheer (2023) aimed to identify problems in the VAS department, investigate root causes, and suggest corrective actions to improve overall performance and efficiency. The paper utilized Pareto analysis as a quality tool to analyse warehouse value-added services (VAS) data for a third-party logistics (3PL) service provider. In order to analyse the causes and effects of logistics services, Ishikawa diagram is used to identify and systematically select different causes that could lead to a certain effect in logistics processes (Stefanova, 2021; Tsou & Hsu, 2022). The paper also aims to provide a model for building the Ishikawa diagram and a procedure for its construction, as well as to discuss the use of the "5 Whys" method and the "5W2H" method for identifying root causes of problems.

Methodology

Data Collection

The numerical data was collected from direct observation at the case study area. The data was collected based on time consuming for each MDA labelling process activities using stopwatch. The primary objective of data collection is to analyse the time consumption (from starting process until the stocks become finish good) of the 18 MDA labelling activities, spanning from picking stock to stock put away. Each activity's time will be recorded to pinpoint the activities with the highest and lowest time consumption using stopwatches. No specific sampling strategy was conducted, as every shipment undergoes time study. Shipments, pre-alerted by the transporter three days prior, are expected three times a week on average. Data collection for the pre-intervention phase spans from April to September 2023. This six-month duration provides a robust dataset, allowing for the calculation of monthly averages for each shipment. As mentioned earlier, the study encompasses 18 distinct activities related to MDA

labelling, ranging from the initial stock picking to the final stock put away. Figure 1 summarizes the 18 activities.

Figure 1: Activities in the MDA sticker labelling

Data Analysis

The analytical approaches used for this study are Pareto diagram and Cause and Effect analysis using the Ishikawa diagram. The first crucial step in utilizing a Pareto chart is clearly defining the problem or issue under investigation, establishing the basis for the analysis. The second step is gathering the data of time taken for each activity related to the identified problem from various sources. The third step involves categorizing the data, organizing the collected information into groups or categories, with a focus on facilitating the analysis of patterns and trends. In this specific case, the data is classified into 18 activities of MDA labelling, where each shipment is segregated into one group, streamlining the process for calculating the monthly average. The fourth step is to calculate the frequency of the data, in order to identify the most contributed activity in terms of time consumed in overall activity.

The fifth step is calculating the cumulative frequency. The sixth step is to calculate the percentage of each category. The percentage is calculated by times 100 of equation 1.

$$\textit{Percentage of total labelling activities} = \frac{\textit{Time consumed in seconds (S)}}{\textit{Overall time consumed in seconds (S)}}$$

Eq. (1)

In the sixth step, the Pareto chart is developed using the categories and their corresponding percentages, arranging bars in descending order of importance. The final step is analysing the Pareto chart. The aim is to interpret the Pareto chart by identifying the most significant categories contributing to the problem and focus efforts on addressing major categories to have the most impact on resolving the issue. From this, the vital few can be identified as those categories embodying the Pareto principle, where 20% of the issues contribute to 80% of the problems.

The next analysis is by creating the Ishikawa diagram, also known as a fishbone diagram, where only 20% of the issues are analysed during its creation. In the context of this case study, the Cause-and-Effect Analysis plays a pivotal role, initiated through a thorough observational process. To commence the analysis, problem areas are categorically identified within six crucial dimensions as per Figure 2 which are Man, Machines, Material, Method, Environment, and Measurement. Each of these categories represents a potential source of challenges contributing to labelling process inefficiencies. This categorization framework serves as a comprehensive lens to scrutinize and understand the multifaceted nature of the identified issues. It allows for the identification of primary causes for the outcomes (effects) and facilitates the implementation of corrective and preventive actions (Stefanova 2021).

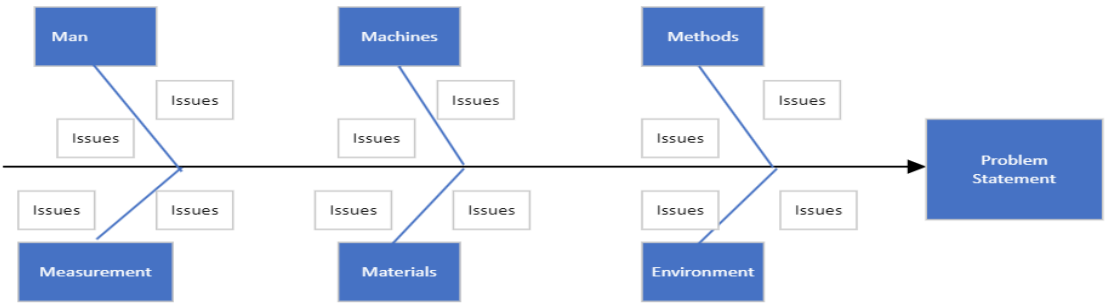

Figure 2: Fish bone diagram

Findings And Results

The results start with the data collection, involving the gathering of relevant information regarding the frequency of different types of defects or issues. This data serves as the foundation for the subsequent steps and should be comprehensive and accurate to yield meaningful insights as per Table 1. The time consumed for each activity is the primary data to measure.

Table 1: Example of data tabulation the 2nd step.

Process/Activity	Unit of Measurement (UOM)	Time Consumed in Seconds (S)/UOM	Time Consumed in Minutes (Min)/UOM
Let down the pallet at staging area	Pallet	2767	46.11
Park the pallet at staging area	Pallet	2593	22.61

The third step involves categorizing the collected data into distinct groups or types based on the nature of the issues. The cause of delay will be categorized based on the findings result from the fishbone diagram, and the data will be tabulated as Figure 3.

		BEFORE	AFTER	
PROCESS / ACTIVITY	UNIT OF MEASURE /UOM	TIME CONSUMED IN SECOND/ UOM	TIME CONSUMED IN SECOND/ UOM	CAUSE OF DELAY
SORTING BASED BY BATCHES	EA	634	604	MIX BATCH IN ONE PALLET
PICKING STOCK	PALLET	381	312	LACK OF AUTOMATION
COMPLETE AND CLOSE MASTER PACKAGING ORDER	EA	307	305	LACK OF TRAINING/BEST PRACTICES

Figure 3: Finding result category in each activity.

Once the data is categorized, the next step is to determine the frequency or count of each issue category as in Table 2.

Table 2: Frequency of cause of delay occurred for each activity.

Row Labels	Count of PROCESS / ACTIVITY
LACK OF AUTOMATION	1
LACK OF COHESIVENESS AND PLANNING	1
LACK OF TRAINING/BEST PRACTICES	6
MIX BATCH IN ONE PALLET	1
SPACE CONSTRAINTS	9
Grand Total	**18**

Cumulative frequency calculation is the subsequent step, where the frequencies of categories are added from the highest to the lowest as in Figure 4. This cumulative view offers insight into the collective impact of the identified issues, emphasizing the significance of certain categories over others.

PROCESS / ACTIVITY	UNIT OF MEASURE /UOM	TIME CONSUMED IN SECOND/ UOM	TIME CONSUMED IN SECOND/ UOM	CAUSE OF DELAY	PERCENTAGE OF TOTAL LABELLING ACTIVITY	CUMMULATIVE PERCENTAGE OF TOTAL LABELLING ACTIVITY	ADDITONAL REMARKS
LET DOWN STOCK AT STAGING AREA	PALLET	2767	1873	SPACE CONSTRAINTS	21%	21%	SPACE CONSTRAINTS
LOCATE PALLET AT PUTAWAY BIN	PALLET	2593	1620	SPACE CONSTRAINTS	18%	38%	SPACE CONSTRAINTS
PARKING PALLET AT STAGING AREA	PALLET	1357	1265	SPACE CONSTRAINTS	14%	52%	SPACE CONSTRAINTS
BRING STOCK AT VAS AREA	PALLET	1053	964	SPACE CONSTRAINTS	11%	63%	SPACE CONSTRAINTS
SORTING BASED BY BATCHES	EA	634	604	MIX BATCH IN ONE PALLET	7%	70%	MIX BATCH IN ONE PALLET
PICKING STOCK	PALLET	381	312	LACK OF AUTOMATION	3%	73%	LACK OF AUTOMATION

Figure 4: Percentage and cumulative per labelling activities

The percentage of total labelling activities and cumulative percentage of total labelling activities were calculated and sorted in ascending order from largest to smallest. One crucial aspect of the research involves the validation of data pertaining to the causes of delays in various MDA labelling activities. Figure 5 illustrates the relationship between time consumption in seconds and MDA activities.

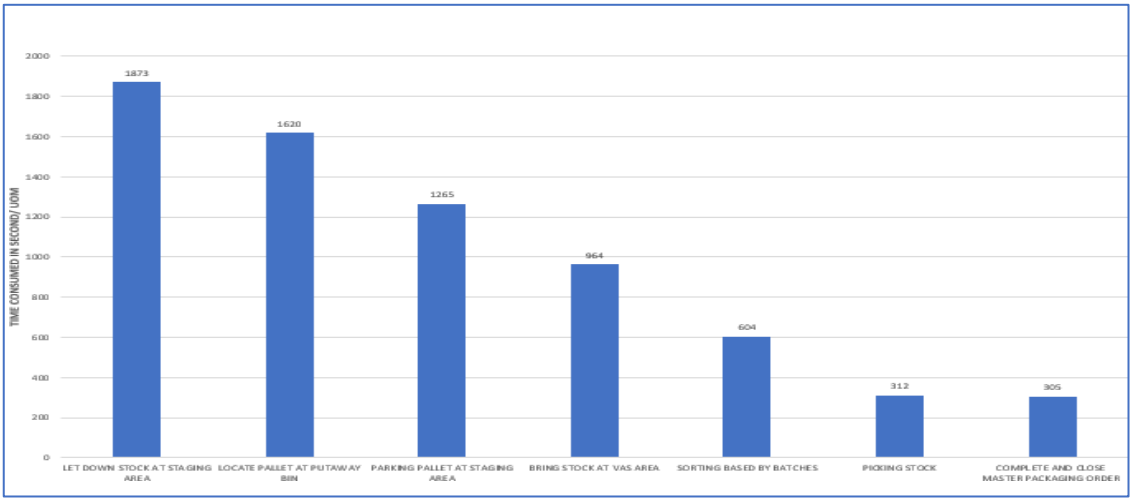

Figure 5: The relationship between time consumption in seconds and MDA activities

Another essential facet of the study revolves around validating the relationship between space availability influences the time consuming for each activity. The objective is

to guarantee that the data accurately portrays how space constraints impact the efficiency of activities related to MDA labelling. Through meticulous validation, insights into the spatial dynamics affecting the workflow are sought, with the goal of optimizing space utilization for improved efficiency. Hence, in this paper, the following two criteria are proposed to be measured as an outcome of this study which are the Percentage of reduction time consuming after layout improvement and Mitigation of reduction in cause of delay based on 20/80 in Pareto principle.

Conclusion

In conclusion, data validation is a cornerstone of the research methodology, encompassing the confirmation of accuracy, reliability, and relevance of collected data. Each aspect of validation aligns with the study objectives, contributing to well-informed decision-making in the pursuit of optimizing the MDA labelling process. As we navigate through these dimensions of data validation, the goal is to refine and implement strategies that not only address current challenges but also pave the way for a more efficient and effective MDA labelling workflow.

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