Simplification of the Weighing Process in the Raw Material Dispensing Unit

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Abstract

The weighing of excipients on the Rapid Material Unit for buffer formulation takes too long to be completed. The leading causes of this problem are the need for more standardization throughout the process, the inefficient distribution of excipients, and the lack of training for manufacturing personnel. The weighing process was studied to reduce the time it takes to complete a weight campaign. It was found that by creating a new design structure for the fragmentation and adding the instructions to the operational documents, 3.15 hours were reduced, enabling the process to become more agile, therefore increasing its productivity.

Introduction

Janssen Cilag located at Gurabo, is a pharmaceutical company. Janssen is divided into two major areas: Solid Molecule (SM) and Large Molecule (LM) business units. SM focuses on pill manufacturing, and LM on biologics manufacturing. The project was developed in the LM Business Unit or Parent. Currently, Parent has two main products: Remicade and Spravato. The project will focus on the first one, Remicade, specifically on the Raw Material Dispensing Unit (RMDU). The RMDU area is where Remicade's manufacturing starts, where all the excipients (sucrose, monobasic and dibasic) are weighted for buffer formulation. Currently, the weighing process is carried out in campaigns (five batches in one weight).

One batch consists of sucrose (38,000 g) in six containers, monobasic (167.3 g) in 3 containers, and dibasic (463.6 g) in three containers. For each campaign, 30 disposable containers are used; monobasic and dibasic containers cannot be reused. It was identified that the weighing process takes approximately 12 hrs. to be completed (9.4 hrs. weighting excipients and 3 hrs. in documentation). Therefore, the project's scope was focused on the weighing process, and its goal was to reduce from 12 containers to eight. The expected future state would consist of five containers to weigh sucrose (38,000 g), one for monobasic (167.3 g), and two for dibasic (463.6 g).

Objectives

The objectives of this project are to:

- Reduce weight processing time by 31% by implementing a new distribution of excipients in stainless steel containers.
- Reduce container waste generated in the weighing process by 50% using a new distribution of excipients.
- Reduce data entries by 25% in the weighing process, operational procedures, and forms.

Methodology

To improve the weighing process in the RMDU, it is essential to consider the activities carried out, the average performance time, and so on. It is necessary, as well, to determine if the current resource utilization is adequate so the system runs as expected. DMAIC Methodology, a data-driven quality strategy intended to improve processes [1], was used for this study. The structure of DMAIC encourages creative thinking within boundaries, such as keeping basic techniques, products, or services. DMAIC is the acronym for Define, Measure, Analyze, Improve, and Control.

Results and Discussion

Current State

The project's main objective is to reduce the containers used for the weighing process. One batch consists of sucrose (38,000 g) in six containers, monobasic (167.3 g) in three containers, and dibasic (463.6 g) in three containers (refer to Table 1).

A data collection plan was developed to identify the tools and parameters to solve the problem. It was decided that a time study needed to be performed to understand how long an associate takes to complete a weighing in the RMDU. The study was conducted in March 2023 during the first shift, where two associates were selected for shadowing. As part of the study, average, normal, and standard times were calculated for the process (see Table 2). An allowance of 5% was given for each computed time. A sample size of 10 for each excipient weighted was obtained.

Table 1
Fragmentation Maximum per excipient

Excipient	Fragmentation	Container weight per batch
Sucrose	30	5 containers of 7,000 g. 1 container of 3,000 g
Monobasic	15	2 containers of 61.6 g. 1 container of 44.0 g.
Dibasic	15	2 containers of 170.8 g. 1 container of 122.0 g.

Table 2
Time Study Results (in minutes)

Excipient	Average Time	Normal Time	Standard Time
Sucrose	63.50	66.68	63.34
Monobasic	29.40	30.87	29.33
Dibasic	21.80	22.89	21.75

Solution

The new fragmentation structure for one batch consists of five containers of sucrose, one monobasic monohydrate container, and two dibasic dihydrate containers (refer to Figure 1). Since the number of containers used for the weight was reduced by 50%, the associates will only use 25, 5, and 10 containers for the weighing (refer to Table 3).

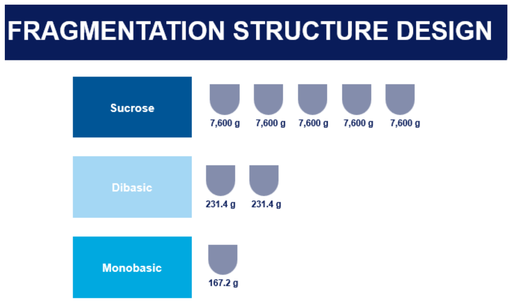

Figure 1
New Fragmentation Structure Design

Table 3
Time Study Results (in minutes)

Excipient	Fragmentation	Container weight per batch
Sucrose	25	5 containers of 7,600 g.
Monobasic	5	1 container of 167.2 g.
Dibasic	10	1 container of 231.4 g.

The time study performed in the RMDU area helped to understand how long it takes to complete the weight for one batch (refer to Table 3). It was concluded that weighing the three excipients takes 1.91 hrs. per lot. Since the weighing is carried out in campaigns (five batches), the total time for a campaign is 9.55 hrs.

Future State

A new time study was performed (refer to Table 4) to confirm if the new fragmentation design reduced the time of the weighing. It was concluded that the time was reduced to 1.28 hrs. per batch, and the campaign was reduced to 6.40 hrs.

Table 4
Time Study Results (in minutes)

Excipient	Average Time	Normal Time	Standard Time
Sucrose	52.70	55.34	50.07
Monobasic	11.40	11.97	10.83
Dibasic	16.70	17.54	15.87

Conclusions

The project's main objectives were simplifying the weighing process to become more agile and increasing labor productivity and time effectiveness by distributing excipients grams in fewer containers. It can be concluded that all the goals set for this project were achieved. The weighing process time was reduced by 32.98% with the implementation of the new distribution. Also, since the new structure uses fewer containers, waste was reduced by 50%. Operational documents were reviewed and updated with further instructions for weighing, and data entries were decreased by 25%..

The main finding of this paper is that the change in the number of fragments has no impact on how the process is carried out except to update the number of fragmentations in the RMDU-related operational documents—also, a cost avoidance of approx. $13,000 will be obtained at the end of the year since the number of containers used was reduced. It can be concluded that any process can be improved; it only takes thinking outside the box and trying to do things differently. The weighing process for other products can be evaluated to conduct the same analysis. Also, processes can be standardized to reduce non-conformances and improve performance. It is essential to provide strategic training to manufacturing associates to guide them to follow the new improvements made to the operational process. Strategic training will improve the performance of the associates and will prepare them to execute at the best time possible. Implementing a mentoring system to improve performance and increase motivation is essential to increase productivity.

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References

[1] ASQ. (2023). *The define measure analyze improve control (DMAIC) Process.* Available: https://asq.org/