Drug Product Process Development Storage Capacity at Amgen's AML7x

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Abstract *— The project aimed to increase the storage capacity for the drug product process development team in AM17x building at Amgen. Storage process and operation improvements were identified through the use of the lean concept. Warehouse data collection was conducted to gain understanding of available materials and the warehouse was found to have 94% overcapacity. After the improvements and redesigns in the storage areas, the storage capacity in AML7x duplicated for a total of 202 material locations based on pallet space.*

Key Terms *— AML7x, DMAIC, DPPD, Six Sigma, Capacity, 5s*

INTRODUCTION

Amgen is a biopharmaceutical company and one of the world's largest independent biotechnology companies. Amgen's current specialty is in human therapeutics. It focuses on areas of high unmet medical need and the improvement of health outcomes and people's lives. Some of Amgen's successful drugs are Neupogen, Prolia, and Vectibix, which have been used to treat low white blood cell counts, osteoporosis, and colorectal cancer, respectively [1].

The AML7x building in Amgen Puerto Rico is currently used by the Drug Product Process Development (DPPD) department to store materials used in different testing and validation activities. In AML7x, the DPPD team stores equipment in a state of development and/or for qualification and their materials. Development activities continued increasing with the amount of test material causing excess inventory over 94% of capacity. Accordingly, excess inventory disables location and consumes spaces. Therefore, currently there is no storage space for future projects in this building and the DPPD department needs to rent external storage. Thereby, the objective of this project was to increase the storage capacity for the drug product process development group in AML7x Amgen. To accomplish the objective, Lean tools and the DMAIC methodology were used through the project.

LITERATURE REVIEW

DMAIC Methodology

The DMAIC methodology is part of Six Sigma tools and is a usefully methodology that could be used to improve processes. It is a structured approach to problem solving that could be applied to any process. In the same way, the methodology aid to reduce variance, improve costs, quality, and among others. Each letter represents the phases that make up the process methodology [2], as follows:

- Define the problem, opportunity for improvement, the project goals.
- Measure process performance.
- Analyze the process to determine root causes of variation and poor performance.
- Improve process performance by addressing and eliminating the root causes.
- Control the improved process and future process performance

Congestion and Excess Materials

Congestion and excess materials within a warehouse could occur due to three deficiencies. The first by having too much adequate inventory in the warehouse. Also having poor storage management. Excess inventory in a storage area can clog aisles, creating safety hazards, decreased work productivity, among others. Also, the materials could end up mixed together. Space is the cause of the limitations mentioned above [3].

Congestion causes extra work when moving a product for which you have no location. This means moving "Product A" to another location to take out this other "Product B". Then the people in charge will start storing things in the aisles. They will use the staging space for new material. The warehouse could run out of space due to excessive materials by outdated inventory, and high demand [4].

However, when this occurs and expanding operations may not be an option, the warehouse can be redesigned, inventory management improved, and off-site storage used. [5] Related to redesign and inventory management within the warehouse, space maximization can be done in different ways such as:

- Extending storage vertically
- Using a mezzanine
- Reducing aisle width
- Using underutilized spaces
- Storing materials in short-term rail cars
- Adding locations that cover half a pallet space of storage

The use of racks to create more space is one of the most common options in warehouses. There are different types of racks such as: pallet racks, cartoon flow racks, cantilever racks among others. The type of rack to choose will depend on the use, the inventory management strategy within the warehouse and the type of material to be stored [6].

On the other hand, there are five principles in inventory management. These principles are: identified what has value, inventory flow, move inventory only when necessary, make changes and continue to apply continuous improvement through the DMAIC methodology. These inventory management principles help reduce waste, reduce costs, increase capacity, and increase profits within an organization. In the same way, 5s is one of the most used tools to improve a warehouse. This tool helps visual management within an organization. This tool has the objectives of reducing waste and improving processes which is composed of five pillars: Classification, Organization, Cleaning, Standardize and Improve [7].

METHODOLOGY

As motioned before, the project followed and was analyzed according to the DMAIC methodology. The following are the details regarding the project phases.

Define Phase

The AML7x building in Amgen is used by Drug Product Process Development (DPPD) department to store materials to be used in different testing and validation activities. There was not sufficient space to relocate or locate new materials at the AML7x DPPD storages area. The inventory increased proportionally; therefore additional external storages were required. The storage capacity did not allow to receive or locate new materials or equipment for future projects. Additionally, it was not in compliance with EHS standards. Therefore, a Project Charter was designed to present the project to the management. In the Project Charter different topics were defined such as: statement of the problem, project objective, business case, project schedule, project scope and project members. The tool was used for management approval.

Measure Phase

An inventory was carried out to get an idea of what the state of the warehouse was. During the inventory, several areas of opportunity were identified. While the inventory was taking place, opportunities were noted and identified to evaluate them in the next phase along with the data collected. In AML7x, the storage areas are divided into three cages. Therefore, each cage was identified by numbers to evaluate each one separately and then obtain a total inventory value. The total of storage cages is three.

The inventory of each cage was carried out by employees assigned to support the executions and implementations of the project. In the same way, the owner of each pallet and material stored inside the cage was identified. In addition, a current layout was created to have knowledge of where each pallet

or material is located, since there was none, nor a system that maintains each material in a specific location. Table 1 presents the area of each cage and the number of pallets. It can be seen that they combine for a total area of 2296.92 ft^2.

Table 1
Storage of Materials at AML7x

Storage Area	Area (ft^2)	Pallets in Cages QTY	Pallet Capacity
Cage 1	1483.68	67	65
Cage 2	406.62	20	18
Cage 3	406.62	18	18
Total	2296.92	105	101

Analyze

According to the data collected, it was possible to evaluate the current capacity of each cage taking into consideration the existing layout and the areas of opportunities that exist regarding the handling of material in the warehouse. Figure 1 shows the amount of excess material in each cage as well as the total excess material in AML7x. For the total excess material, the materials stored in containers outside the building were considered.

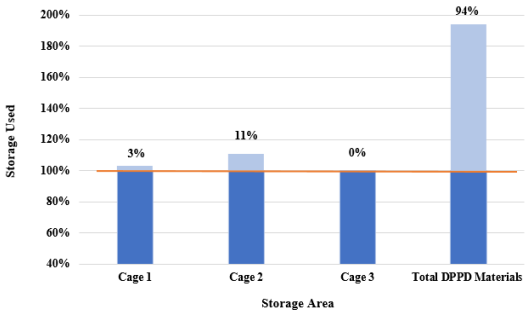

Figure 1
Storage Capacity in AML7x

The orange line represents 100% capacity in the given storage area. Percentages above 100% represent excess material. Therefore, the total excess of DPPD group materials was 94%. From that 94%, 14% were inside the cages and the remaining in areas that were not storage for materials or in external containers, as mentioned before. On the other hand, a fish bone diagram was used to identify and categorizing the potential causes of the problem, as shown in Figure 2. According to the diagram, there were six potential causes for the problem. They were identified and the proposed solution and action to be taken were established, as shown in Table 2.

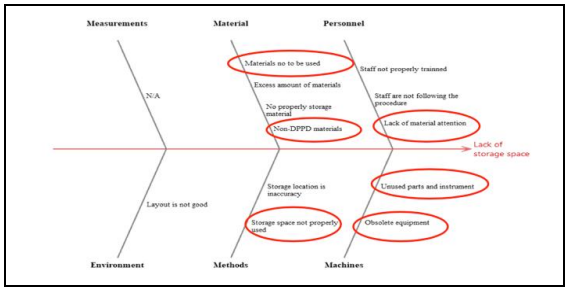

Figure 2
Cause and Effect Diagram

Table 2
Analyze of Causes

No.	Problem cause	Proposed Solution	Action
1	Materials no to be used/, Unused parts or instrument	Materials, equipment, parts or instrument not in use will be discarded.	Materials / Equipment or parts will be discarded per SOP-427608. Perform a 5s in the storage areas
2	Obsolete Equipment	Equipment not in use will be discarded.	
3	Unused parts or instrument	Parts or instrument not in use will be discarded.	
4	Non- DPPD materials stored	Materials needs to be removed or discarded from the storages area allowing extra space location for DPPD materials.	Perform a 5s in the storage areas
5	Lack materials attention	Train staff on how to properly handle their materials.	Improve Standard Operating Procedure
6	Storage space not properly used	Use racks for store materials in the cages to avoid unnecessary pallet space. Re-layout the storage areas.	Implement racks in Cages 1,2, and 3, organized per material type. Divide the racks in different sections (bulk material section, boxes section)

Improvement

Before performing the new layout in the storage areas, a 5s was performed in each storage cages. All materials that had no added value were discarded such as obsolete materials, excess material and material that did not belong to the DPPD department. As part of the organizing phase, two alternatives were designed for organizing the storage areas:

- Alternative 1: Is based on dividing the type of material by cages (syringes, vials, materials, final pack materials and devices). Cages 2 and 3 have racks designed to place loose boxes. However, only Cage 1 has bulk materials and there are no racks.
- Alternative 2: Is based on dividing the materials by cages as well, but in this alternative, Cage 3 is designed with the ability to place 50% of bulk pallets and 50% of loose boxes for racks.

The Alternative 2 to organize and design the warehouse was selected after a decision matrix performed, as shown in Table 3. Implementation of Alternative 2 duplicated the storage capacity in the warehouse. In other words, the warehouse capacity increased to 202 pallet spaces.

Table 3
Decision Matrix

Legend: 4 = more relevant 3 2 1= Less Relevant		Alternative 1		Alternative 2	
	Weight	Rating	Total	Rating	Total
(Less) Time to implement	3	4	12	4	12
(Less) Cost	4	4	16	3	16
Capacity (Increase)	4	3	12	4	16
Resources utilization	2	2	4	2	4
Total			**40**		**44**

Control

An electronic tagging system was created to identify inventory materials. An employee will handle requisitions or storage of materials in their locations. The standard operating procedure of handle and storage material at AML7x will be updated and approved in Amgen's documentation system. After that, all personnel who works or needs to manage material in AML7x DPDP storage areas will require a training to perform actions at the storage areas. On the other hand, a 5s will be performed once a week in order to maintain the storage organized.

CONCLUSION

As a result of implementing Alternative 2, the design in the storage areas duplicated the capacity. The materials that were outside the cages were located in the storage areas. In the same way, the external containers that were used to store material were eliminated. Therefore, the cost of external warehouses was eliminated as well.

In this project, several lean concepts were applied, such as 5s in the storage areas, which helped to visualize the areas of opportunities in greater detail. On the other hand, the dates that were established in the Define phase to complete the DMAIC activities were met. However, work is ongoing on the activities of the control phase and will continue as future activities.

As mentioned in the control phase, the warehouse will have access only for Drug Product Process Development (DPPD) personnel and will be controlled through a card reader system. These personnel must be trained before to have access in the storage areas. The materials will have their location and will be counted through SAP system. SAP will maintain the inventory and the material transactions. A person in charge will be handling any order or storage of material. In this way, the control and monitoring of the warehouse will be maintained.

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