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#### Abstract

The Amgen Manufacturing Limited formulation room was impacted by the increase of forecasted variable demand for 2019 and 2020. During the evaluation it was found that decreases in demand for certain months caused an increase of idle time for manpower up to 87.4 hours. The current headcount for the formulation room is 40 associates. Total cost of associate time ranges from \$20-\$23 per hour. Time for breaks, transit and gowning and documentation of laboratory testing were identified as the major offenders for this change. The creation of a labor model of the formulation area permitted the detailed evaluation of all the activities performed by the associates. Using distribution of activities within associates, reducing non-value-added activities and a proposal to implement parallel activities when performing the job, the total headcount remained the same but idle time was reduced to 32.60 hours and cost was reduced by $10.86 \%$.


Key Terms - idle time cost reduction, headcount, manufacturing labor activities, non-value-added activities.

## Introduction

Amgen Manufacturing Limited site in Juncos, PR is responsible of the manufacture, inspection and packaging of pharmaceutical products. Among those products, there are solid dosage for treatment, vials and syringes for chronic and terminal diseases. The AML-14, which is the drug product manufacturing building is responsible of the formulation, mixing and filling of vials and syringes. As scope for this paper, the formulation room is responsible of receiving the right amount of drug substance in order to prepare the needed amount of mixed chemicals to produce the drug product using portable tanks. These tanks are then transported to the filling area in order to fill either
vials or syringes. The formulation room need to adhere to the filling area schedule in order to provide on-time drug product to fill vials or syringes to comply with business demand. During the Management Review of forecasted demand presented by the Supply Chain Department, the July planning cycle showed an increase of $70 \%$ on the formulation area in all the products manufactured. As part of the evaluation reaction, management increased total headcount equally between shifts for the rest of 2019. Variation was observed on the formulation area performance due to idle time buckets during manufacturing processes increasing idle time cost in man hours. This evaluation will permit management at Amgen decide whether they need to allocate resources to comply with demand requests and reduce idle time costs. A labor model created as part of this project analysis will allow management and manufacturing supervisors in the formulation area of drug product adjust current status to business needs.

Using direct time studies of the activities performed in the formulation area it was found that total labor hours was 61.07 represented in Table 1 which allocates a total of 40 associates per 4 shifts. An analysis of non-value-added activities within the processes observed and the use of a labor model to adjust demand receive for future planning cycles will allows the formulation area to adjust and comply with business requirements maximizing the total time available to perform the job.

Table 1
Total Labor Hours

| Year | Area | Process Equipment/Month | Labor Hours |
| :---: | :---: | :--- | :---: |
| 2019 | COP/SOP | CIP/SIP Labor Time Per Tank (hrs) | $\mathbf{6 . 1 4}$ |
| 2019 | Buffer | Total Labor Hours (CIP/SIP + Buffer) | $\mathbf{7 . 1 0}$ |
| 2019 | Formulation | Fixed Weight | $\mathbf{7 . 7 8}$ |
| 2019 | Formulation | Protein Concentration | $\mathbf{1 0 . 6 0}$ |
| 2019 | Formulation | Pool \& Mix | $\mathbf{4 . 8 3}$ |
| 2019 | Formulation | Enbrel | $\mathbf{1 4 . 6 2}$ |
| 2019 | Miscellaneous | Transportation for cafeteria (1 hr. per associate) | $\mathbf{1 0 . 0 0}$ |

## Literature Review

## Capacity analysis in manufacturing lines

Manufacturing lines are found in pharmaceuticals, textiles, medical devices and raw manufacturers companies all over the world. Puerto Rico has adopted manufacturing since the 20th century. Around $46.5 \%$ of medical product comes from the pharmaceutical sites on Puerto Rico [1]. Manufacturing has been affected through time impacting directly cost of units and therefore incrementing the cost of medicine. There are indirect costs within the manufacturing sites that has a great effect on the cost of medicine. The increment in headcount to support demand, overtime, equipment and materials investment, overhead and inventory has caused positive and negative outcomes for most of pharmaceutical and medical devices companies around the world.

Capacity and productivity issues are not only related to manufacturing companies but to Occupational and Environmental medicine programs. Inside the production floor there are hourly paid employee and exempt employees. Normally, hourly paid employees are direct product assemblers that execute the creation of the product and the exempt employees are support management. There are various factors that can occur from the employee perspective that have negative impact to the cost of unit. A study of a total of 4000 hourly paid employees indicated that the highest amount of unpaid days is directly correlated to full absent day [2]. Absenteeism is one of the main drivers of cost increase. When a management decision is to acquire more headcount to comply with demand for a manufacturing line, and this demand is variable through forecasting then idle time comes. Most of the absenteeism drivers are resistant to flexibility within the manufacturing line, habit, sickness, injury or unrelated event [2]. In 2018 the age of adults working in manufacture in Puerto Rico ranges from 35 to 44 were the total of working persons were $1,092,000$. The $46.5 \%$ of this number are employees directly working in manufacturing
facilities [3]. For this reason, manufacturing sites have applied several incentives to maintain employees' long term.

## Analysis Approach

During observation of man related activities, it was found that the total time for all formulation area was 61.07 man-hours which is represented by a total of 40 associates divided within formulation sections and 11.5 hours' shifts. Using forecasted demand for 2019 and 2020 as input for the labor model created in order to represent the process, it was observed that formulation area total man-hours were 372.60 which represents an $81 \%$ of availability to work per associate which is equal to 135,999 hours a year. Idle remaining time was calculated to be 87.40 hours which represented a total of 31,901 idle hours a year. Tables 2 and 3 show forecasted demand for each of the products manufactured through formulation room.

Table 2
2019 Forecasted Demand


Table 3
2019 Forecasted Demand


## Activities Evaluation

Three activities were identified as major offenders from the labor model results: Documentation of laboratory work with a total of 610 hours a year, transit and gowning which
requires associates to move outside the manufacturing room with a total of 80 hours a year and breaks for a total of 60 hours a year. Figure 1 shows the bar chart of major offender activities. Although these activities can be improved using administrative controls, it is known that due to changes in demand for future years major offenders can variate from time to time.


Figure 1

## Major Offenders of Idle Time

Using the higher paid wage scenario for associates, Equation (1) represents a total of $\$ 17,250$ a year in idle time cost.
$(1 * \$ 23 * 750 \mathrm{hrs} /$ year $)=\$ 17,250$

## Results

## Idle time reduction

In order to reduce/eliminate idle time, several factors were considered. Each of the three major offender activities are related to a compliance metric that cannot be removed from business management [4]. During the observations, it was found that laboratory paperwork is performed at the end of each lot and by hand and prevent new lot startup to begin on schedule which caused delays in the manufacturing process. Therefore, it was recommended to perform parallel activities of laboratory paperwork during the CIP/SIP of product and buffer tanks without impacting the critical path of the formulation process. Each associate will complete laboratory paperwork during machine time capture in total labor hours for formulation room permitting the current labor hours to absorb this activity during the manufacturing
process. Therefore, idle time hours reduced from 31,901 to 31,291 per year.

Evaluating transit, gowning and break, major offender of idle time hours, it was observed that total travel time from formulation room to cafeteria and back was 30 minutes per associate. Because of the design of the manufacturing plant, this time is the least travel time for the cafeteria and therefore cannot be reduced. As this travel is required as part of the job, allocation of resources to cover breaks and transit was recommended in order to have a continuous flow of working hours without any idle time. Table 4 shows the benefit of reducing idle time related activities that impact continuous manufacturing flow.

Table 4
Reduction Benefit

|  | Idle Time (HRS) | Idle Time Reduction (HRS) | Benefit |
| :---: | :---: | :---: | :---: |
| Allocating <br> Laboratory <br> paperwork as <br> a parallel <br> activity | 31,901 | 31,291 | $1.91 \%$ |
| Travel time <br> reduction at <br> $100 \%$ | 31,901 | $31,900.50$ | $0.00 \%$ |
| Total Benefit of reduction |  |  |  |

As mentioned in the analysis, total idle time cost per year is $\$ 17,250$ including all major offenders presented. Table 5 represent the idle time cost reduction for the improvement presented above.

Table 5
Reduction Benefit in Cost

|  | Idle Time (HRS) | Idle Time Reduction (HRS) | Total Cost |
| :---: | :---: | :---: | :---: |
| Allocating <br> Laboratory <br> paperwork as <br> a parallel <br> activity | 610 | 610 | $\$ 14,030.00$ |
| Travel time <br> reduction at <br> $100 \%$ | 0.5 | 0.50 | $\$ 11.50$ |
| Total Benefit of reduction |  |  | $\$ 14,041.50$ |

## RECOMMENDATIONS

## Short Term Recommendations

In order for the formulation room to continue reducing costs in idle time, the following recommendations can be implemented:

- Implement a digital logbook in laboratory documentation in order to minimize human error and waiting time.
- Rotate associates in order to minimize impact on breaks.


## Long Term Recommendations

There are other types of improvement that can be performed at a long-range ( 1 to 5 years) scenario because of the complexity of implementation such as:

- Look for solutions on how to use available space in building for a small cafeteria to minimize impact on manufacturing processes.
- Reduce machine downtimes.


## References

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