

Idle Time Reduction in Formulation Room

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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)	6.14
2019	Buffer	Total Labor Hours (CIP/SIP + Buffer)	7.10
2019	Formulation	Fixed Weight	7.78
2019	Formulation	Protein Concentration	10.60
2019	Formulation	Pool & Mix	4.83
2019	Formulation	Enbrel	14.62
2019	Miscellaneous	Transportation for cafeteria (1 hr. per associate)	10.00

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 vary from time to time.

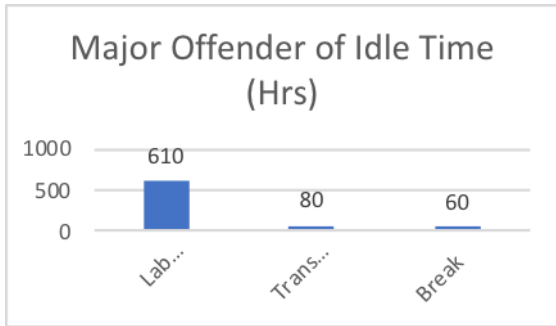


Figure 1

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.

$$(1 * \$23 * 750 \text{hrs/year}) = \$17,250 \quad (1)$$

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 Laboratory paperwork as a parallel activity	31,901	31,291	1.91%
Travel time reduction at 100%	31,901	31,900.50	0.00%
Total Benefit of reduction			1.91%

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 Laboratory paperwork as a parallel activity	610	610	\$14,030.00
Travel time reduction at 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.

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