Idle Time Reduction in Formulation Room

Mitchelle M. Berrios Colon
Advisor: Hector Cruzado, PhD, PE
Master in Engineering Management
Polytechnical University of Puerto Rico

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. 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%.

Introduction

Amgen Manufacturing Limited site in Juncos, PR A biotechnology innovator since 1980, 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. The formulation room which is responsible of the mixing of the drug product needs 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.

Objective

As part of the variation observed on the formulation area performance due to idle time buckets during manufacturing processes increasing idle time cost in man hours. in demand, management increased total headcount equally between shifts for the rest of 2019. Therefore, the evaluation will permit management decide whether they need to allocate resources to comply with demand requests and reduce idle time costs.

Methodology

Methodology used for this project was divided into three phases of execution and in conjunction with a labor model created in excel data was collected in order to capture idle time in man related hours

Phase I
- Direct observation on manufacturing processes in formulation room
- Identification of idle time mayor offenders
- Determine standard times of man related activities

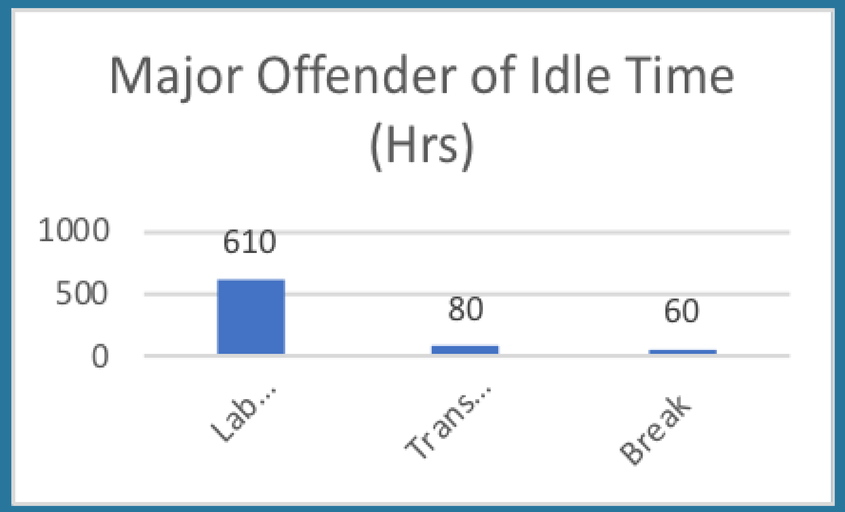
Phase II
- Creation of formulation room labor model
- Identification of total working hours
- Identify labor model baseline and current headcount needed

Phase III
- Implement improvements on opportunities observe
- Analyze headcount calculations with improvements
- Calculate idle time in man hour with improvements observe
- Implement labor model in formulation room shift structure
- Propose a plan of continuous improvement and labor model quarterly

- Total time studies performed for man related activities

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

- Three activities were identified as major offenders from the labor model results: Documentation of laboratory work with a total of 610 hours a year



Results

	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%

	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

Each of the three major offender activities are related to a compliance metric that cannot be removed from business management [1]. 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.

Conclusions

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.
- 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

[1] Tunälv, C. (1992), Manufacturing Strategy – Plans and Business Performance, International Journal of Operations & Production Management, Vol. 12 No. 3, 4-24.