

Formulation Process Optimization

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Abstract

The field of biologics drugs development continues to grow and is becoming increasingly competitive. The manufacturing of biological medicines is a complex process that consumes a large amount of resources and time resulting in higher manufacturing costs in comparison of small molecules therapies. The lean manufacturing philosophy provides tools to identify areas of opportunity to optimize these processes by eliminating waste as activities that does not add value to the product. Buffer formulation is an inherent step in the biological product formulation process. Using the Value Stream Map tool in our buffer formulation process helped to find areas of opportunity that will allow recommendations to optimize the formulation process. In this way, it is possible to reduce manufacturing costs, increase capacity and have a better allocation of resources.

Introduction

The costs for the development and manufacture of biological products are highly expensive mostly due to the complexity of the process. Market competition continues to grow and new products are in development. After considering these points, becomes evident that the industry must actively pursue continuous improvement with the application of tools that enable process optimization and maintain competitiveness in the market. These tools could not only improve the quality of the final product but also help to reduce total production costs and increase overall effectiveness and capacity, thus contributing to the success of the company.

Methodology

The DMAIC methodology was used to evaluate and improve the process.

Define

Project Charter

Project Lead:	Saul Hernandez	Start Date:	Q1 2023
Sponsor:	Noel Torres	End Date:	Q4 2023

Problem Statement

Drug Product facility manufactures biologics parenteral drugs commercialized to treat a wide range of conditions from autoimmune to cardiovascular. Product demands are increasing and new products in development are pending regulatory approval. Drug product formulation requires an extensive amount of time and resources. It is required to maximize efficiency and capacity to support product demand.

Project Goals

- Reduce Formulation process lead time.
- Increase Formulation capacity.

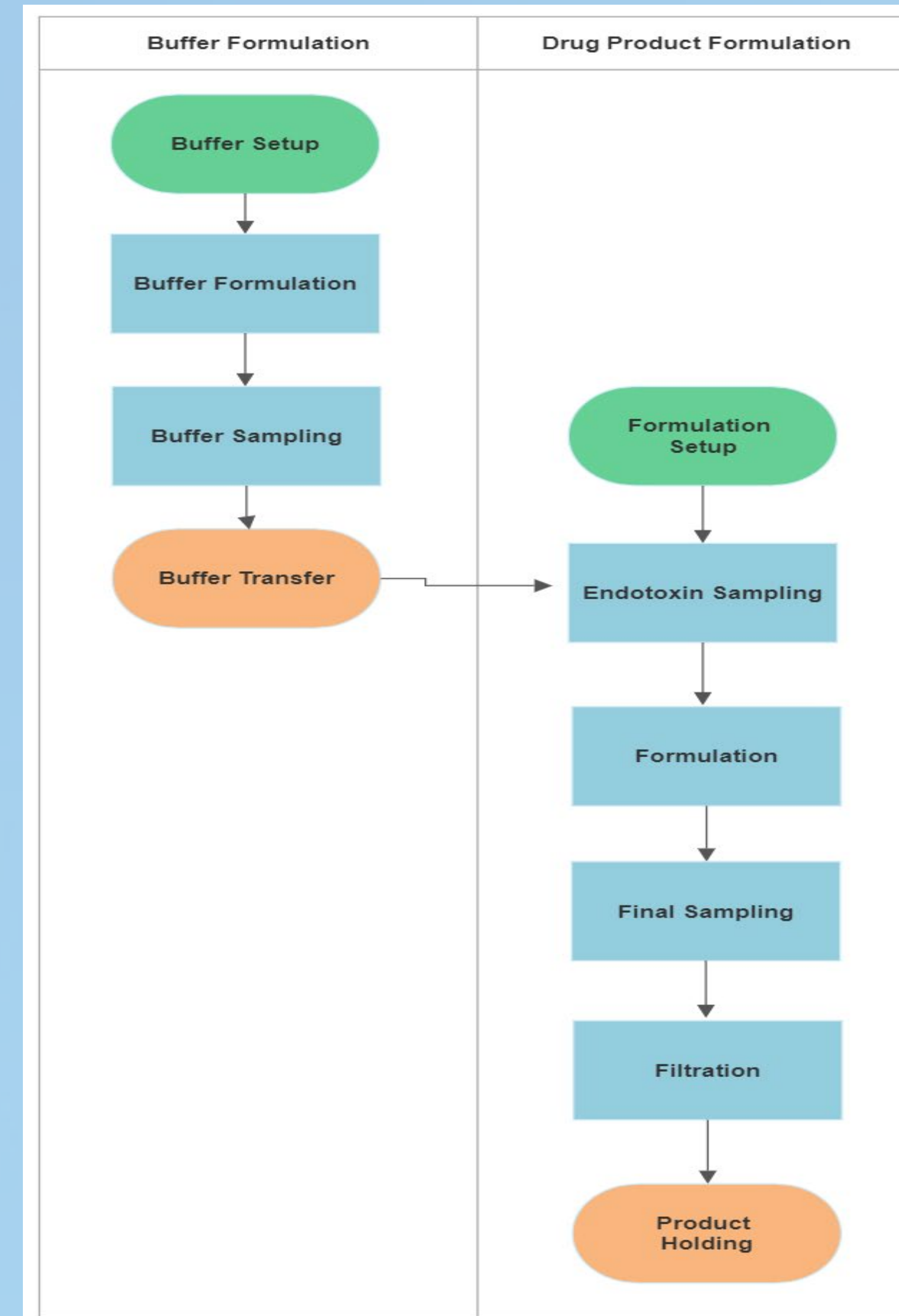
Business Benefits

- Formulation labor cost reduction
- Maximize Profitability after formulation capacity increased.

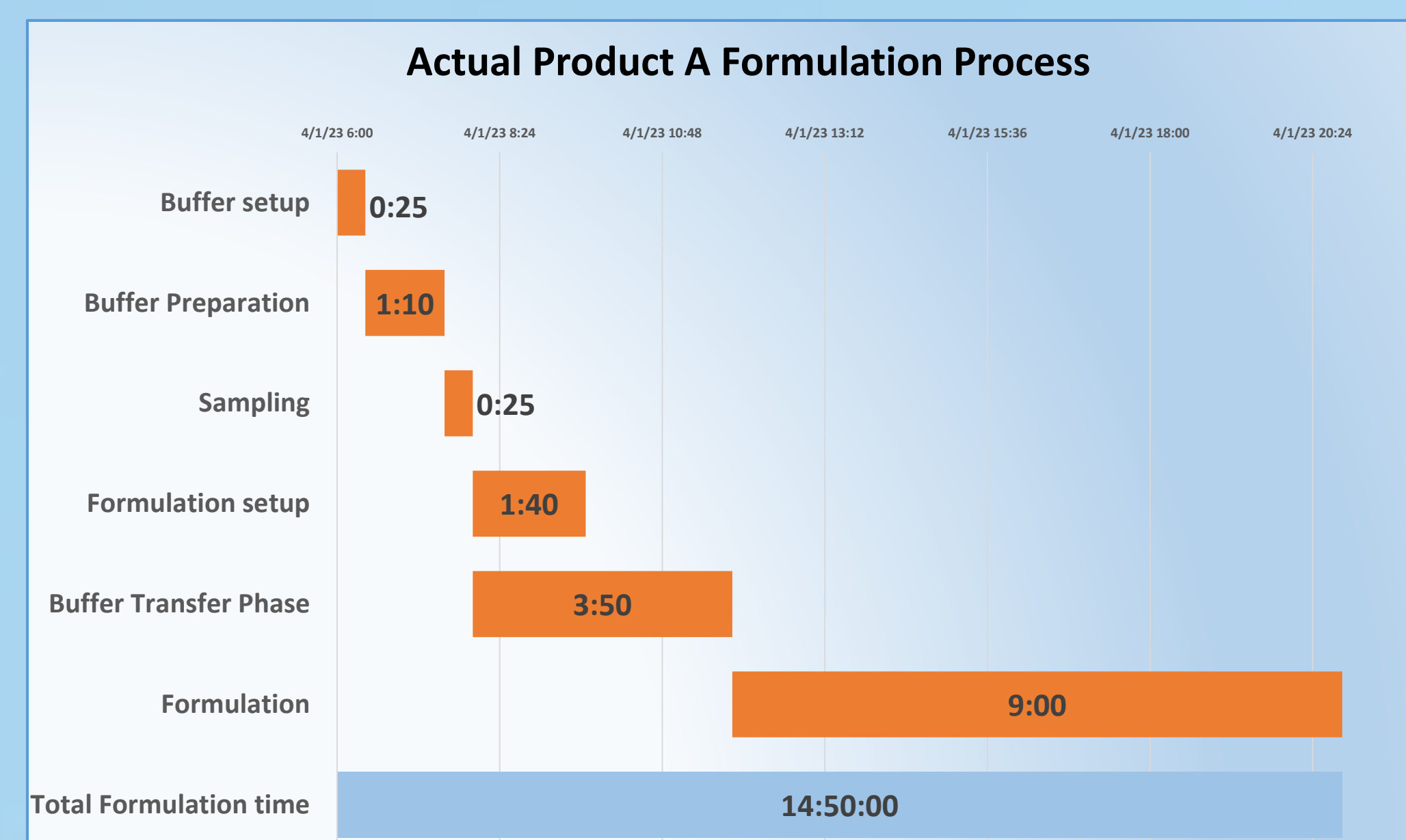
Team Members

- Manufacturing Associates
- System Owners Team
- Information System Team
- Quality Assurance
- Manufacturing Specialists
- Automation Engineering

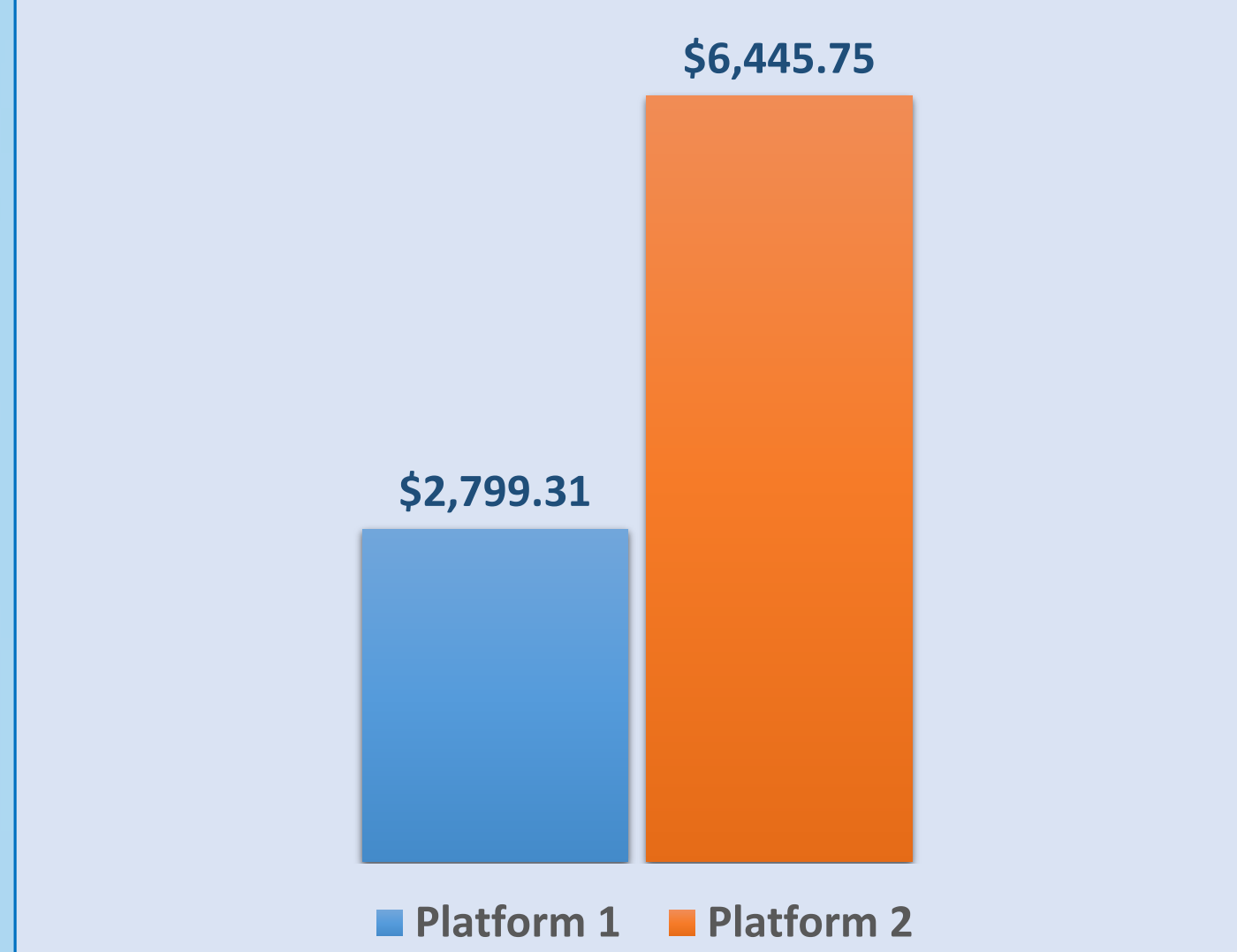
Formulation Process Map



Measure

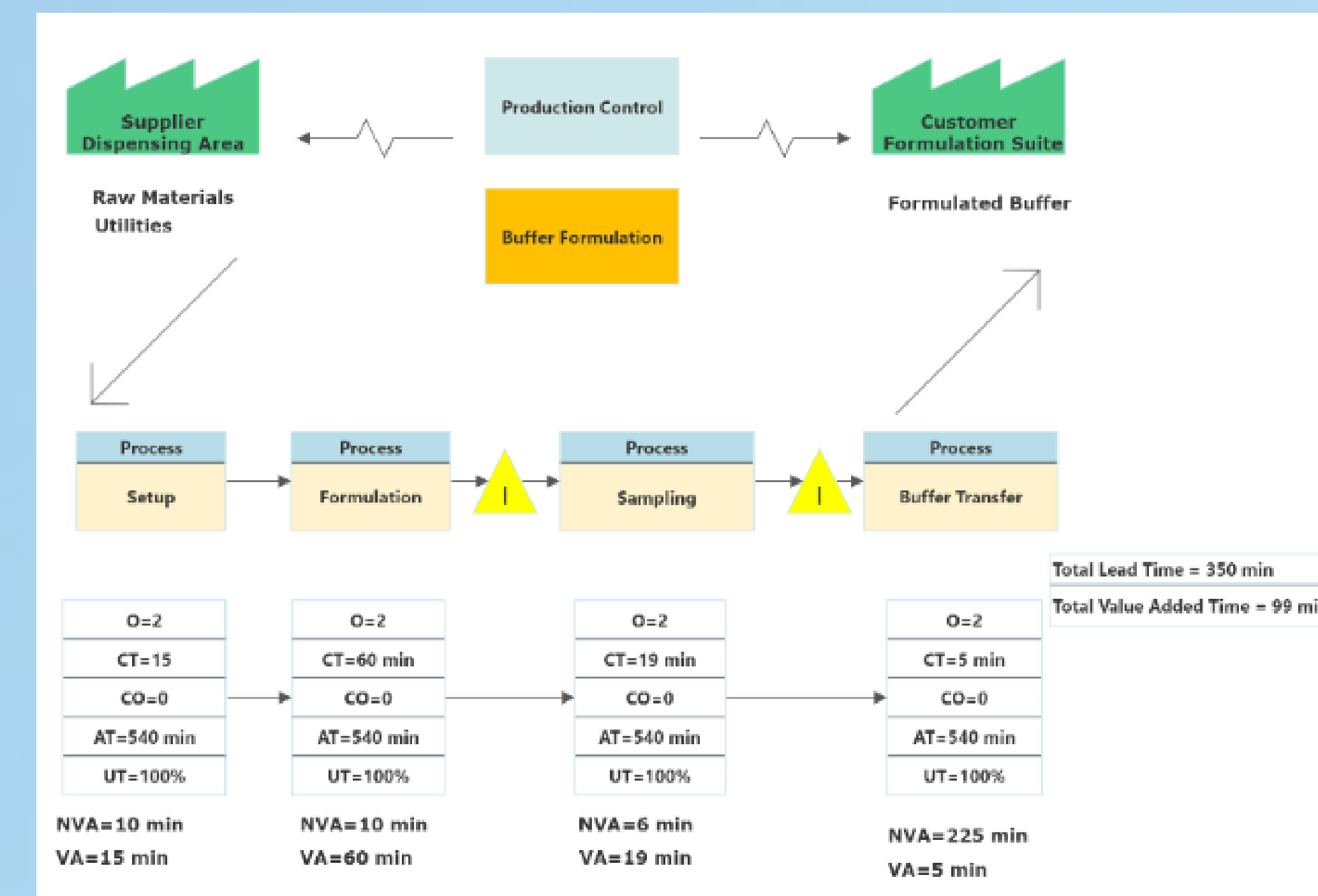


Actual Direct labor Cost per Batch

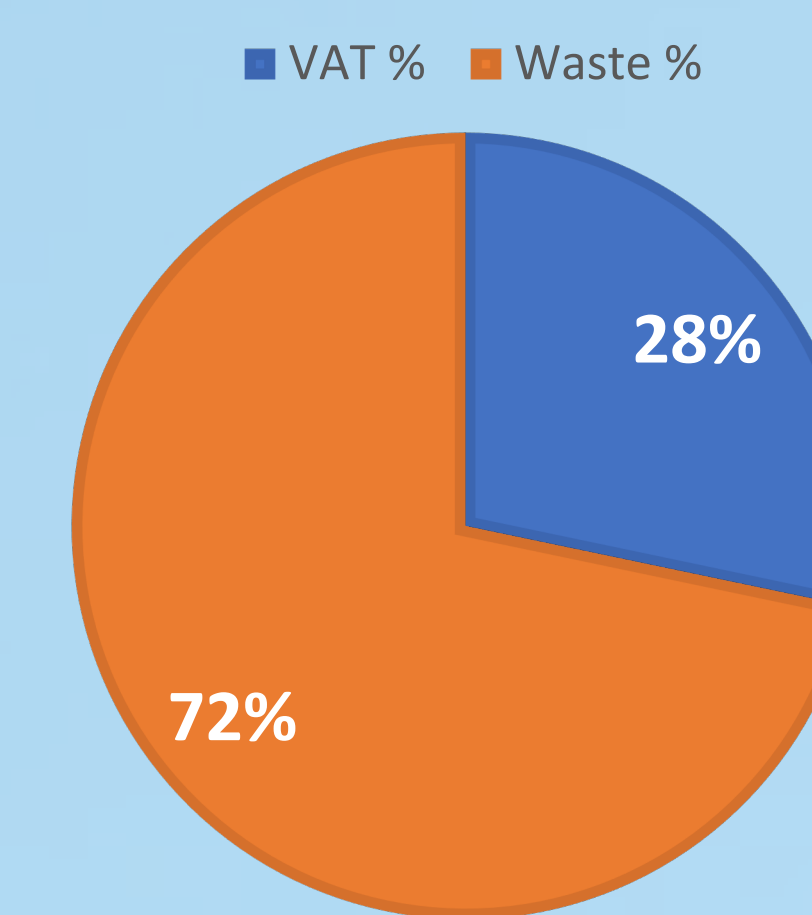


Analyze

Buffer Process Value Stream Map

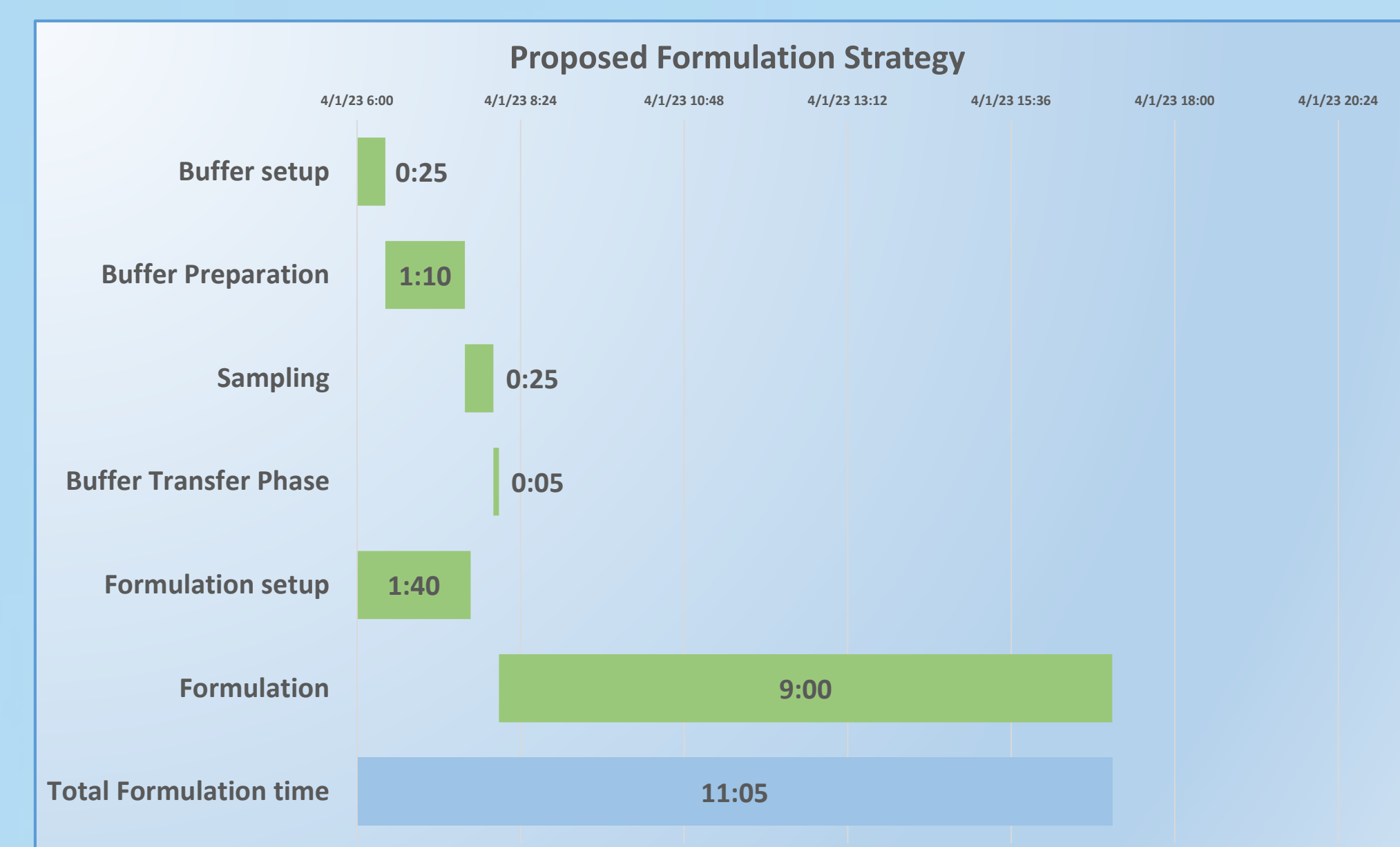


BUFFER FORMULATION VSM RESULTS



Improve

Proposed Formulation Strategy

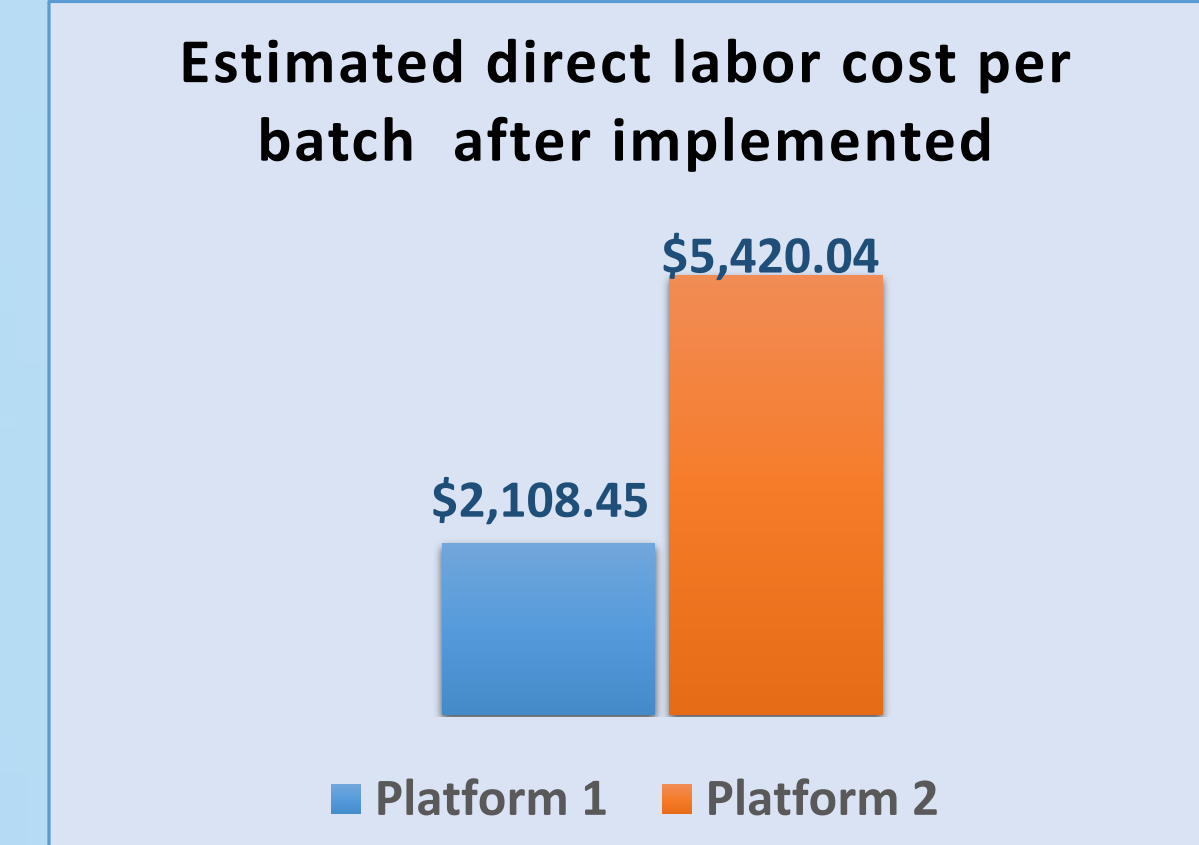


A new Formulation strategy is being proposed to optimize the formulation process time. By starting the formulation setup simultaneously with the buffer setup and transferring the buffer to the formulation suite after sample taking, the waste of waiting will be eliminated and significantly reduce the formulation time by 220 minutes or 3.66 hours. This reduction is applicable for both Formulation Platforms.

Control

Control phase monitor the process after change implementation.

Expected Results



Previous Forecast includes 338 batches/yr	Expected time Savings and increased capacity
199 Platform 1	1,237 hours
139 Platform 2	Up to 63 batches from platform 2

Conclusions

While the market share and the demand for biological products continue increasing, it is necessary to identify areas of opportunity that allow us to optimize manufacturing processes and increase capacity. Waiting is the easiest identifiable waste in Lean. The application of the VSM in the buffer formulation process helps us to easily identify the waste as the idle time during the buffer transfer phase. With the implementation of the proposed strategy, the formulation process time will improve by **25.28%** and save approximately **\$280,059.22** in direct labor costs. This strategy is simple but effective. With the reduction in the formulation time, there is flexibility and agility to adjust the manufacturing schedule to meet market demand and the capacity to adopt the new products currently in development.

Future Work

Lean tools are essential to achieve a state of excellence in manufacturing. Further area to evaluate is the analytical lab to improve the formulation in process-testing.

Acknowledgements

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