



Abstract

This research project was focused on the implementation of an alternate material used in the preparation of buffers of the production for Product X in a biotechnology company. Buffer are solution that can resist pH change upon the addition of an acidic or basic components, which major role is to stabilize pH of living systems. Due to the constant changes in the market because of the COVID-19 pandemic, the identified alternate material was implemented using the DMAIC methodology. This project pursues mitigating the cost increase of the primary material, but mostly it will secure the business continuity of Product X.

Introduction

The biotechnology industry has been impacted by the constant changes on the market of raw materials because of the new reality associated to the COVID-19 pandemic. The main objective of the biotechnology companies is to always secure the delivery of the products to the patients with high quality. Therefore, identification of alternate materials to address the unexpected cost increase or shortages in the raw materials market, became an imperative to secure the delivery of the products to patients.

Background

From 'The White House' official government page it describes that shortage and supply-chain disruptions are significant but most of the time transitory. On the Figure 1, is presented the supply chain disruptions by sector where the first position take place by the Manufacturing sector. Demand are increasing and industries present cascading issues on the supply-chain that provoke shortages and abrupt price increases. At the same time, this material impacts the consumer prices. Some disruptions in the industries may be caused by unexpected strong demand with low inventory levels, supply shock due by failure or natural disaster.

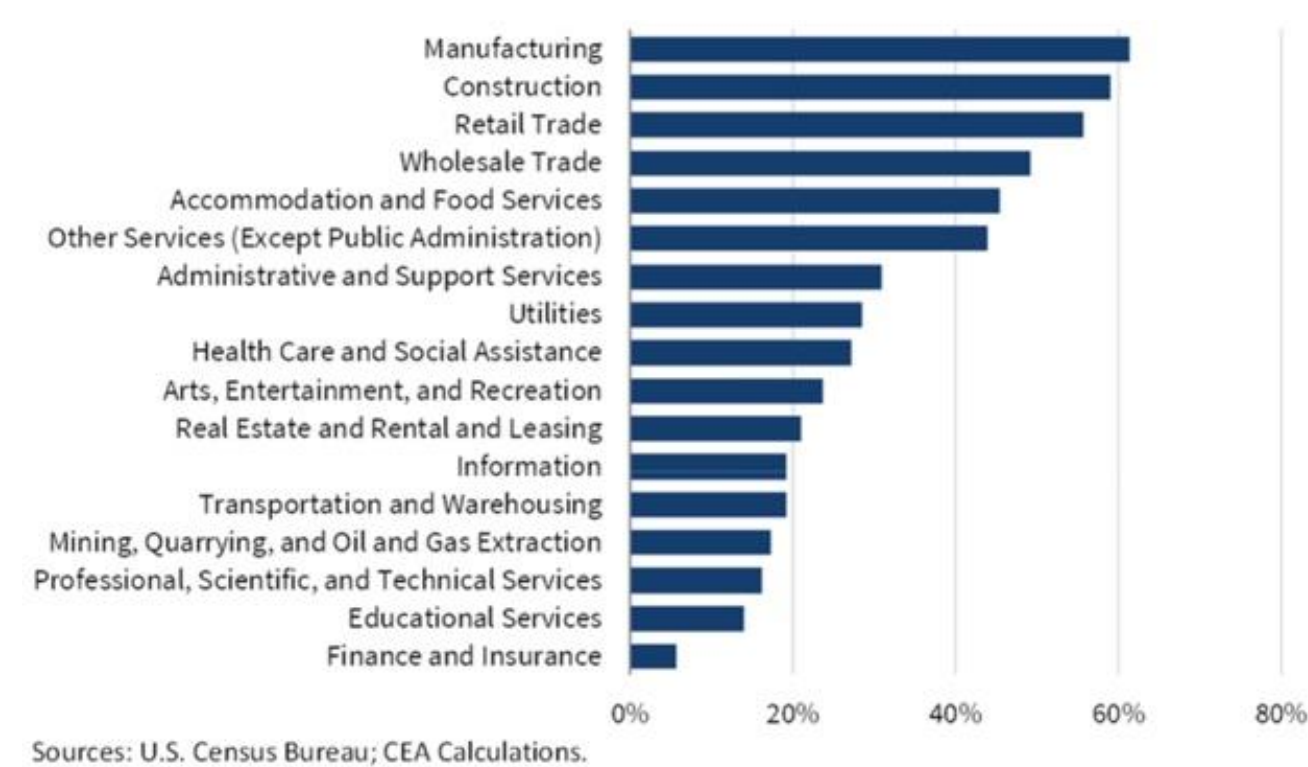


Figure 1: Supply Chain Disruptions by sector [1]

One way that manufacturing companies try to mitigate the abrupt changes of the supply chain is to build safe inventory levels. At the same time, they identify materials that have experienced significant market changes and identify alternative materials for them. The incorporation of the alternate material on the process helps industries comply with their demands, secure business continuity and on-time delivery.

Problem

The cost increase or scarcity of raw materials puts product supply at risk. The goal, is reduce the impact because of the primary material cost increment, comply with the 2022 production schedule and secure delivery of Product X.

Methodology

The implementation of the alternate material was using the DMAIC methodology. The Quality Council of Indiana defines DMAIC as a problem-solving methodology used to improve processes. The acronym stands for Define, Measure, Analyze, Improve, and Control for the specific problem [2]. The methodology can be used for product or service lean six sigma projects to comply with the outcomes and benefits expected.

Define: Focusses on understanding who the customer are, their requirements and expectations and the core business process involved with project boundaries.

On the Define stage it was used the following tools:

- **Project Charter:** Document that outlines the why, what, how, and who of the project to be discussed with team members and stakeholders
- **SIPOC:** Tool used before the work or project begins to identify all the important elements of the improvements. SIPOC takes into account the suppliers, inputs, improvement process, outputs, and customers. Finally, it's always recommended to have the SIPOC diagram visible to all the team members (chart, transparency, or a wall in an identified area) and be discussed with the project sponsor, champion and stakeholders involved.
- **VOC:** The Quality Council of Indiana book defines the Voice of the Customer (VoC) as "a way to listen to the customer's needs and perceptions". This is a critical step for any project and must be a detailed plan to gather and collect feedback.
- **Fishbone:** Also known as a Cause-and-effect diagram where is identified the problem statement and potential contributing factors divided in categories.

Measure: Focusses on extent the issue by quantifying it with different techniques. These techniques can be divided into four main categories process analysis, data collection, measurement systems and process capability analysis.

Analyze: This step entailed data collecting and process mapping in order to identify root causes of faults and areas for improvement. It also identifies performance gaps between present and desired performance, as well as objective statistical processes and confidence limitations.

Improve: This stage focuses on improving the target process by coming up with innovative ways to solve and prevent difficulties.

Control: Focuses on regulating improvements in order to keep the process on track and avoid reverting to the "old way." Simultaneously, create a continuous monitoring plan by institutionalizing the improvements made through system changes.

Results and Discussion

Define

A VOC was made to understand business need, and the scope and expected outcome of the project. Then, a cross-functional kickoff meeting was performed to understand the impacted areas, the modifications and actions to be addressed, and receive feedback from the Subject Matter Experts (SME's).

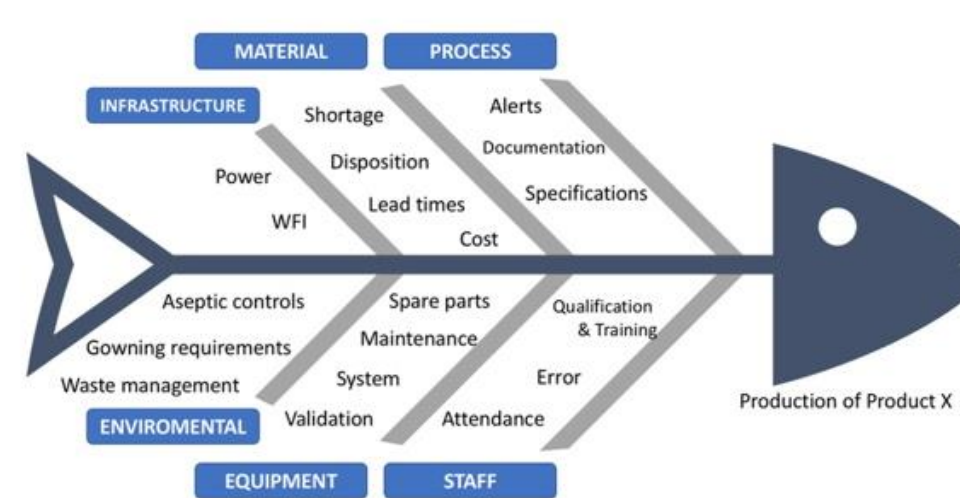


Figure 2: Fishbone Diagram

Then, a project charter was developed in collaboration with the SME's and Quality representatives, see Figure 3.

Figure 3: Project Charter

In addition, the SIPOC diagram, shown in Figure 4 was generated to identify the element of the improvements before the starting project.

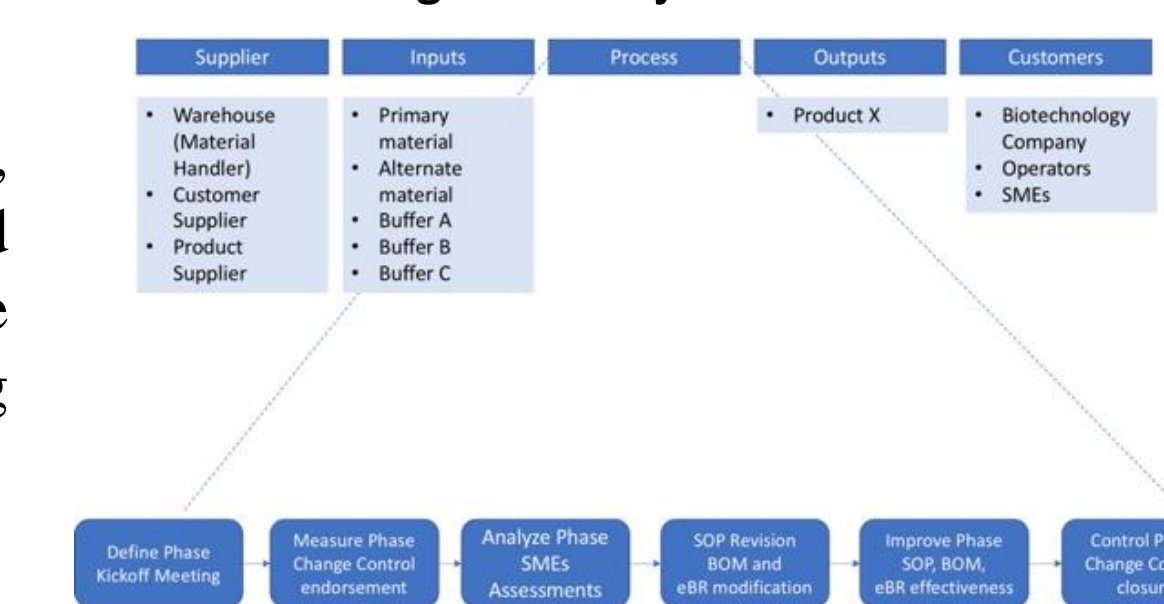


Figure 4: SIPOC Diagram

Measure

Pre-assessments were requested from the different functional areas and identify the tasks that may need to be completed as part of the project. These pre-assessments along the Project Charter were used to present the project in the Change Control Review Board. Both, Manufacturing and Quality management endorsed the project, which enabled the initiation of a change control record.

Analyze

The pre-assessments were formalized by each of the functional area SME's and documented in the change record. Then, the record was promoted to the pre-implementation phase.

Improve

The team will perform the modification needed to include the alternate material in the Bill of Materials (BOM), Standard Operating Procedures (SOP's), and Electronic Batch Record (eBR).

These procedures must be revised by the SME's and verified by quality until the effectiveness of them. Is important to have a scheduler representative to understand the best moment to do the changes without impacting the schedule of the manufacturing area. This action will complete the implementation of the project and will mitigate the possibility of interruption of supply.

Control

Finally, is expected to finish the documentation of the record until it closures. In addition, after the completion, a gap assessment will be performed with the manufacturing area and sponsor to understand if a new area of opportunity is identified and to validate the accuracy of the Define phase.

Conclusions

In conclusion, this project led us construct a path to implement the alternative material used in the production of buffers for the production of Product X by May 30, 2022. By performing the DMAIC methodology, it was understood by the VOC the importance of the change to secure business continuity and on-time delivery. Modification of the SOP, eBR and BOM for the incorporation of the alternate material will be completed on-time to comply with the implementation date of May 30, 2022.

Future Work

Find primary materials with similar scenarios for subsequent phases and identify an alternate material to ensure company continuity.

Acknowledgements

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References

[1] "Why the pandemic has disrupted supply chains," *The White House*, 30-Nov-2021. [Online]. Available: <https://www.whitehouse.gov/cea/written-materials/2021/06/17/why-the-pandemic-has-disrupted-supply-chains/>. [Accessed: 08-May-2022].

[2] B. Wortman, *Lean six sigma primer*, 2nd ed. West Terre Haute, IN: Quality Council of Indiana, 2018.