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 Manufacture Competitiveness

Abstract

A small regulated company established in Puerto Rico developed a cost improvement project on a Quality Area to stay competitive. The main objective was to reduce the number of samples sampled for X and Y areas. Also, according to the evaluation those samples quantities already stored were reduced and the sample orientation at storage was changed. The implementations were performed with data integrity, high quality, within Regulatory and Quality Management approval. Plan Phase was used to investigate the situation where the Visual Management 5'S was applied. During the data analysis was implemented a solution plan on the Do Phase. Meanwhile on Check Phase it was evaluated that implementation accomplished the project milestones. Though on Act Phase a cost saving of \$85,784.82 was met and around 50% of samples sampled were reduced. It was confirmed with a Hypothesis Test for the Mean with alpha 5% and it was found that the reduction was completed.

Introduction

A small regulated company develops a cost improvement project on a Quality Area to stay competitive. The project consists on samples reduction for cost saving and to make more space available for samples storage. This project was performed using lean techniques as Deming Cycle as the principal tool. Meanwhile the project could be accomplished using Visual Management 5'S Methodology.

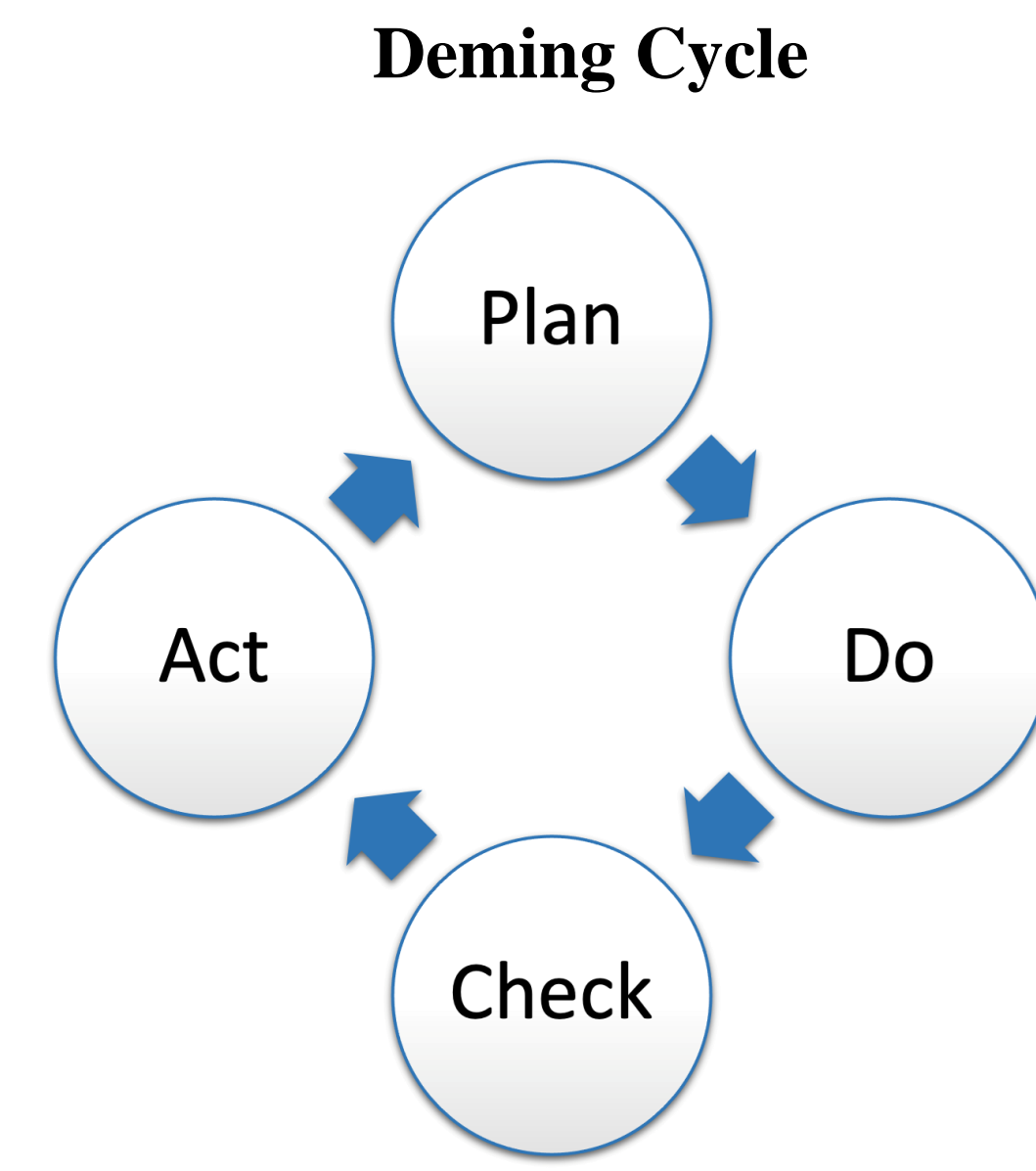
Background

The audit background is important for this project since the processes should be performed meeting with regulations and data integrity. The small regulated site established on Puerto Rico had suffer several changes on the last years and audits are more frequent than usual despite the observations had been minors. The factor that impacts the site is the competitiveness with other sites around United States that manufacture similar products. The parent site always evaluates costs and in the process several consolidations of products and sites had been take place. The small sites need to stay competitive accomplishing quality and overall performance. Therefore, improvement projects are important to maintain these small sites competitive within quality and profitability.

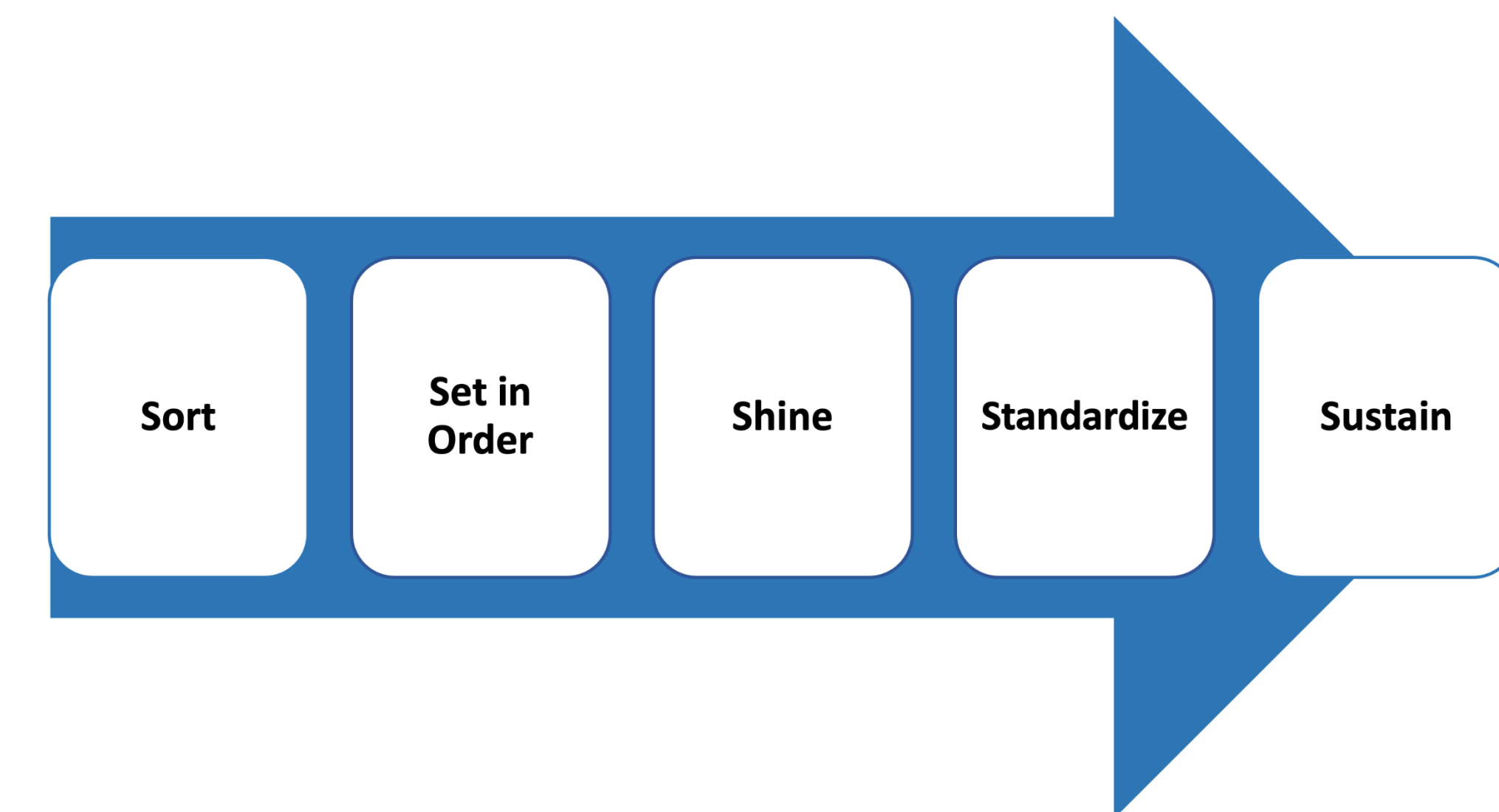
Problem

There is a small regulated company located at Puerto Rico that manufacture products for United States and Canada which had been under several audits and had suffer several changes on the last years. Now the company is under evaluation among other companies that manufactures similar products outside Puerto Rico of the same parent Site. Therefore, several cost improvement projects had been implemented on the last year, but there is still challenging the situation on the small site. Then a cost improvement project was suggested to reduce costs on a Quality Area to help accomplish the company main goal, reduce cost by \$80000 within 12 weeks reducing the sampling by 50%.

Methodology



Visual Management 5'S Methodology



Results and Discussion

Hypothesis Test for the Mean

It is expected to have a %Reduction of 50%

Sample Size	%Reduction
N = 5	
1	50.0%
2	50.0%
3	50.0%
4	46.2%
5	54.2%

H₀: μ = 50%
 H₁: μ ≠ 50%

Test with Known Variance (Normal Distribution)

Variance 1.0%

Hypothesis Test Results	
μ	0.50
σ	0.33%
\bar{X}	50.08%
N	5
Z_{exp}	0.541
P _{value}	0.588
α	0.05

There is not enough evidence to reject H₀, μ is equal.

Test with Unknown Variance (Student T Distribution)

Hypothesis Test Results	
μ	0.50
s	2.86%
\bar{X}	50.08%
N	5
T_{exp}	0.062981
P _{value}	0.952803
α	0.05

There is not enough evidence to reject H₀, μ is equal.

Results and Discussion

The sample orientation on storage before evaluation was horizontally. This orientation let 133 cartons stored by shelf.

The sample orientation on storage after evaluation is vertically. This orientation lets 163 cartons to be stored by shelf, 30 cartons more per shelf after implementation.

Samples Evaluation on X and Y Quality Areas

Product	X Area					Y Area				Total Cost Saving \$
	Total Lots to be manufactured on 2022	Total of Samples Sampled Originally	Total of Samples that Could be Sampled after Evaluation	Total of Samples Returned to Lot to be Commercialized	%Reduction	Total of Samples Sampled Originally	Total of Samples that Could be Sampled after Evaluation	Total of Samples Returned to Lot to be Commercialized	%Reduction	
A	21	174	87	87	50.0%	1106	506	600	54.2%	\$ 76,596.12
B	15	24	12	12	50.0%					\$ 2,514.60
C	5	12	6	6	50.0%					\$ 469.50
D	5	39	21	18	46.2%					\$ 2,521.80
Cost Saving of External Storage not used since project implementation offers 45 shelves to store samples of Product A for X and Y Areas which consists on 51% of storage.										\$ 3,682.80
Total \$ 85,784.82										

Conclusions

The execution of lean techniques for cost improvement in a Quality Area of a small regulated company established in Puerto Rico was concluded. The project charter, SIPOC and process flow chart tools helped to find out the overview of the project for improvement. Although the Visual Management 5'S Methodology was a guide to execute the cost improvement of this project with the lean technique Deming Cycle (PDCA). The project milestones were accomplished.

	Project Time Period	Project Cost Saving	Reduction Plan on Sampling	Availability of Storage	Does the goal is meet?
Theoretical	12 weeks	\$80,000.00	50%	50%	Yes
Experimental	10 weeks	\$85,784.82	50% confirmed by Hypothesis Test for the Mean	51%	

Future Work

Although the cost improvement was accomplished further evaluations should be performed to evaluate samples storage availability. It should be part of the work culture to come back and evaluate the Deming Cycle for future evaluations.

Acknowledgements

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References

- [1] M. Fritz, "Data Integrity and Warning Letters", NSF International, Ann Arbor, MI, USA, 2020. https://d2evkimvhatqav.cloudfront.net/documents/ph_data_integrity_warning_letters_white_paper.pdf?mtime=20200623104054&focal=none
- [2] Food and Drug Administration. (2018, Dec.). Data Integrity and Compliance with Drug cGMP: Questions and Answers – Guidance for Industry. [Online] <https://www.fda.gov/media/119267/download>
- [3] M. Neumeyer, "Data Integrity: 2020 FDA Data Integrity Observations in Review", American Pharmaceutical Review, <https://www.americanpharmaceuticalreview.com/Featured-Articles/565600-Data-Integrity-2020-FDA-Data-Integrity-Observations-in-Review/>, (accessed March 14, 2022).
- [4] S.J. Schniepp, "ALCOA+ and Data Integrity", Pharmaceutical Technology, 43, 10, (October, 2019), 77. <https://www.pharmtech.com/view/alcoa-and-data-integrity>