Optimization, Standardization and Revision of the Label Review Policies and Procedures Manual using Lean Six Sigma

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Abstract

The Label Review Department focuses on reviewing other companies label for compliance with FDA regulations by providing a one-on-one service accompanied with a report with recommended changes and a print-ready graphic file. As Covid-19 pandemic started, the organization shifted to a virtual environment that caused time and accessibility effects on the Label Review Policies and Procedures Manual. For this reason, this manual was modified, organized, and optimized to determine time documentation retrieval reduction using Lean Six Sigma methodology. The staff members were participated in a pre and post launch assessment. The new proposed manual was a successful on providing more accessibility, being updated, and becoming a tool for daily tasks. However, no significant time reduction of documentation retrieval due to high variability between staff members time response. Further investigations, analysis and actions must be taken to ensure that the new launched manual reduces documentation retrieval time significantly.

Key Terms *— Standardization, Lean, Six Sigma, Cloud System*

Introduction

To be able to continue assisting different companies around the world during the COVID pandemic, the organization decided to try to move as quickly and operable as possible to remote work. However, the fast transition and daily work basis caused an increment of waste, training flaws and higher time consuming. The combination of Lean and Six Sigma will be used to improve detected values, eliminate, or reduce waste, and optimize the Label Review Policies and Procedures manual. The project focus is to modify, organize, optimize, and implement recommendations and changes for the LR Policies and Procedures Manual to reduce documentation retrieval time.

Background

The Label Review Department consist of 1 Department Manager, 2 Team Leaders and 8 Label Reviewers (staff members). The Department Manager, 2 Team Leaders and 2 Coordinators met to be able to determine the strengths and weaknesses of the post Covid cloud document sharing system of the Label Review Policies and Procedures Manual A policy is a guideline that regulates organizational action which controls the conduct of personnel and the activities of systems. A procedure is the normal method of handling things (the "how to"). Procedures supplement policy guidelines with specific and complete the information users need. Currently, the established cloud document sharing system appears to lack current policies documentation, procedures standardization and personnel has opted out for alternative options instead on accessing to an established system. In other words, the system has become obsolete. During the pandemic, the organization tried saving all required and relevant files in two different locations causing duplication, out of date information, overprocess and more time-consuming process flowcharts.

Problem

From the start of the COVID-19 pandemic, the fast transition to virtual work and daily work basis caused an increment of waste, training flaws and higher time consumption. Currently, the Label Review Policies and Procedures Manual was in a multi-sharing system, not consistent and lacking an upgrade and optimization. By implementing the Lean Six Sigma methodology, the policies and procedures will provide guidance for personnel training, eliminate or reduce identified wastes, develop training tools, increase efficiency and productivity, the development of a spatial organizational arrangement and implementation of continuous improvement. The project focus is to modify, organize, optimize, and implement recommendations and changes for the LR Policies and Procedures Manual to reduce documentation retrieval time Based on the results of the project, the implementation of Lean Six Sigma Methodology could be used for different departments and LR Notebooks.

Methodology

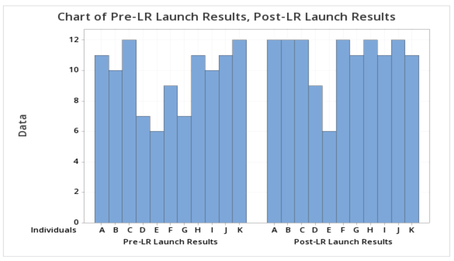
The Label Review Process was observed in order to identify strengths and weaknesses. The original Label Review Policies and Procedures Manual was compared with the observations made in the previous step. The comparison findings were discussed with the Head of Department and two Team Leaders. Afterwards, the Label Review Process Standard Operating Procedures (SOP) and documents in each section of the Label Review Policies and Procedures cloud document sharing system were revised, standardized, reorganized, and optimized by implementing the Lean Six Sigma Methodology. The Label Review Policies and Procedures was reviewed and approved by the Head of Department. The implementation of the 5s Six Sigma created and developed a spatial organization arrangement. The total optimized, revised, and standardized were quantified to determine the new composition of the manual and revisions made. Afterwards, an assessment was performed with the department staff members to determine the before and after the launch of the implementation of changes, recommendations, and revisions to the Label Review Policies and Procedures Manual. Lastly, the findings and results were discussed and presented to the Head of Department, Project Team and CEO.

Pre-Launch Individual Score Results

Individual	Post-Launch Result	Percentage
A	11	92%
B	10	83%
C	12	100%
D	7	58%
E	6	50%
F	9	75%
G	7	58%
H	11	92%
I	10	83%
J	11	92%
K	12	100%
Average	9.6	80%

Post-Launch Individual Score Results

Individual	Post-Launch Result	Percentage
A	12	100%
B	12	100%
C	12	100%
D	9	75%
E	6	50%
F	12	100%
G	11	92%
H	12	100%
I	11	92%
J	12	100%
K	11	92%
Average	10.9	91%



Pre-Launch Time Breakdown per Question

Assessment	Individuals Response (s) A	B	C	D	E	F	G	H	I	J	K	Average
Question #1	38	51	26	24	223	120	40	380	304	11	29	113.3
Question #2	81	29	14	34	22	87	129	34	28	34	19	46.5
Question #3	54	90	23	37	33	54	20	54	168	30	63	56.9
Question #4	25	36	33	23	28	13	13	12	18	14	10	20.5
Question #5	35	38	15	25	55	21	12	17	66	15	17	28.7
Question #6	43	18	23	37	16	16	11	22	33	13	21	23.0
Question #7	73	46	18	21	25	337	71	33	29	14	17	62.2
Question #8	39	15	23	46	46	18	12	21	31	18	16	25.9
Question #9	42	15	28	25	19	71	18	30	29	16	18	28.3
Question #10	86	9	32	46	30	68	24	109	97	39	37	52.5
Question #11	82	15	20	25	71	22	127	46	70	17	17	46.5
Question #12	28	22	19	13	61	218	46	16	48	19	22	46.5
Total time	626	384	274	356	629	1045	523	774	921	240	286	550.7

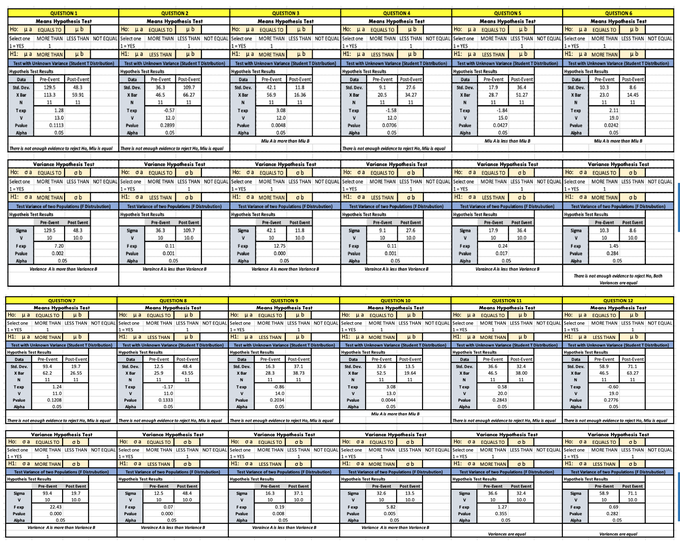
Post-Launch Time Breakdown per Question

Assessment	Individuals Response (s) A	B	C	D	E	F	G	H	I	J	K	Average
Question #1	28	151	13	57	37	13	86	30	76	29	139	59.9
Question #2	19	3	11	6	121	378	45	20	78	45	3	66.3
Question #3	17	3	14	12	13	3	43	5	22	26	22	16.4
Question #4	39	3	20	45	15	6	19	27	41	96	66	34.3
Question #5	86	4	26	87	25	52	98	10	43	29	104	51.3
Question #6	19	3	12	8	25	10	9	15	16	9	33	14.5
Question #7	32	3	53	36	20	64	5	35	18	6	20	26.5
Question #8	21	3	26	61	38	7	58	23	179	33	30	43.5
Question #9	62	3	130	64	38	45	3	24	5	28	24	38.7
Question #10	32	4	15	32	49	7	14	24	13	8	18	19.6
Question #11	15	3	21	22	47	64	13	29	120	40	44	38.0
Question #12	42	145	17	22	40	249	40	25	54	39	17	63.3
Total time	412	328	358	452	474	898	433	267	665	388	520	472.3

Results and Discussion

- The results were limited to the quantity of individuals within the department of the organization and individuals had opportunity to navigate and get to know the new manual for 2 weeks.
- The new Label Review Policies and Procedures Manual was created by developing a spatial organization arrangement focusing on the needs and daily tasks of staff members and process flow charts to be able increase accessibility, efficiency, and productivity.
- The average score results increased 11% compared to the Pre-Launch Score Results. The lowest score corresponds to Individual E score.
- Question 1 average time response reduced from 113.3 seconds in the original Label Review Policies and Procedures to 59.9s representing a 53% decreased.
- For Question 1, 2, 4, 5, 6, 7, 8, 9, 11, and 12, the p-value is greater than (>) α which means there is not enough evidence to reject the null hypothesis. This result indicates that based on the population the Pre and Post Launch mean are the same and are within the same bound.
- For Question 3, 6, and 10, the p-value is less than (<) α indicating that the null hypothesis is rejected and that the Pre-Launch Mean is significantly more than the Post-Launch Mean.
- Question 5 is that Pre-Launch mean is significantly less than the post-Launch as the p-value is less than α. Question 5 establishes that the new Label Review Policies and Procedures Manual did not reduced time for the specific documentation retrieval.
- The possible cause of no significant time reduction may be due to high variability and little adaptation time and normalization of the new Label Review Policies and Procedures Manual.

Mean and Variance Hypothesis Test per Question and Total Average Time



Total

Means Hypothesis Test

Ho: μ a	EQUALS TO	μ b	
Select one	MORE THAN	LESS THAN	NOT EQUAL
1 = YES		1	
H1: μ a	LESS THAN	μ b	

Test with Unknown Variance (Student T Distribution)

Hypothesis Test Results

Data	Pre-Event	Post-Event
Std. Dev.	25.5	18.1
X Bar	45.9	39.36
N	11	11
T exp	0.69	
V	18.0	
Pvalue	0.7516	
Alpha	0.05	

There is not enough evidence to reject Ho, Miu is equal

Variance Hypothesis Test

Ho: σ a	EQUALS TO	σ b	
Select one	MORE THAN	LESS THAN	NOT EQUAL
1 = YES		1	
H1: σ a	LESS THAN	σ b	

Test Variance of two Populations (F Distrubution)

Hypothesis Test Results

	Pre-Event	Post Event
Sigma	25.5	18.1
V	10	10.0
F exp	1.98	
Pvalue	0.852	
Alpha	0.05	

Variances are equal

Conclusions

- The problem was not solved significantly with the development of the spatial organizational arrangement and the implementation of the Lean Six Sigma philosophy due to high variability and short adaptation time.
- The new launched manual provided more accessibility, standardization, process stability and understanding within the department.
- The Training Section provides a new detailed-oriented internal training with up-to-date information and tools reflecting the daily tasks and process flow.
- The email_blurbs_templates section provides the opportunity for Label Reviewers to simply be more productive and efficient in documentation retrieval that could lead to less time consumption in email correspondence with clients in future assessments.
- A quality documentation tracking system was implemented in order to implement the continuous improvement and to start the development of the Quality department.

Future Work

- To perform an investigation, review and analysis to determine the factors affecting the time responses of each Label Reviewer per question
- To administer a follow-up assessment to determine if the time documentation retrieval reduction was significant or not within 3 weeks
- To conduct a survey to provide a qualitative measurement regarding the Label Reviewers feedback and feelings about the new manual.
- To conduct a quality audit every 3 months to ensure that the new Label Review Policies and Procedures is optimized and updated.

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