Optimization, Standardization and Revision of the Label Review Policies and Procedures Manual using Lean Six Sigma at Polytechnic University of Puerto Rico

Joyce M. Rivera Santiago
Masters in Manufacturing Competitiveness
José A. Morales, PhD.
Industrial Engineering and System Department
Polytechnic University of Puerto Rico

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 *— Cloud System, Lean, Standardization, Six Sigma.*

INTRODUCTION & LITERATURE REVIEW

The Label Review department strives to provide comprehensive regulatory guidance to our clients when exporting to the United States as efficiently as possible without sacrificing quality. It is one of the most lucrative departments in the organization. The U.S. Food and Drug Administration (FDA) defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its container or wrappers, or (2) accompanying such an article" which may include packaging, instructions, product inserts, websites, and other promotional material [1]. Labeling mistakes result in more than 22% of all detentions in the United States representing that for every 50 shipments a total of 11 shipments are detained. The Label Review Department focuses on reviewing other companies label for compliance with FDA regulations by providing a one-on-one service with an expert with specialized knowledge in FDA regulation accompanied with a report with recommended changes and a print-ready graphic file. 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. Currently, the organization uses different cloud document sharing system, but the common cloud document sharing system is Virtual Private Network (VPN) connected named LR Server. The transition from office work to remote work was a victory to keep the organization motor running during the pandemic. However, the fast transition and daily work basis caused an increment of waste, training flaws and higher time consuming. From the start of the pandemic, the Label Review Policies and Procedures Manual was in a multi-sharing system, not consistent and lacking an upgrade and optimization. The focus of this project is to update, standardize and optimize of the online organization's Label Review Policies and Procedures Manual using the Lean Six Sigma (LSS) methodology. 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. By implementing the Lean Six Sigma methodology, the policies and procedures will give guidance for personnel training, elimination or reduction of identified wastes, development of training tools, increase efficiency and productivity, the development of a spatial organizational arrangement

and implementation of continuous improvement. During the pandemic, many organizations noticed how obsolete or behind their organization was regarding technology incorporation for a digital transformation. Additionally, the pandemic caused a high demand on cloud document management systems. A cloud document management system can be defined as a web-based data storage and information management application that allows users to access files across different locations and timelines around the world [2]. The cloud document management system can allow organizations to control their files and documents. One of the main benefits about cloud document management system for companies is accessibility. The systems allow documentation to be accessible to workers to connect remotely that enable changes to be update in real time allowing collaboration and communication to be reinforced and propelled. The Lean Six Sigma methodologies to reduce wastes, defect and increase efficiency and results. Lean methodology focuses on efficiency compared to Six Sigma methodology focuses on how effectivity can lead to faster results. It was created by the Juran Triology, which is an approach to planning, controlling, and improving an organization's performance [3].

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 Label Review Notebooks. After launching the new proposed Label Review Policies and Procedures Manual, the Label Review Coordinator will ensure and provide training for all department staff on how to navigate the proposed cloud document sharing system.

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.

RESULTS AND DISCUSSION

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. As previously mentioned, 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. The original Label Review Policies and Procedures Manual is divided into 5 categories which are the following: Email Templates, In Progress-Label Review Procedures, Administrative, LR Product Review and Focus Sessions, SR and other Training. The OneNote cloud sharing system contains a total of 128 files within the previously mentioned categories. The second cloud

system sharing system named the LR Server contained duplicates of the 128 files plus outdated versions of those files (Table 1). By implementing Lean Six Sigma methodology, we were able to identify the following wastes: motion, overprocess, transportation, and overproduction. Each category section was analyzed by identifying the files that were created, revised, included, updated, and omitted. A new proposed Label Review Policies and Procedures Manual was created with 5 categories which are the following: Administrative, LR Product Spotlight, Training, Email_Blurbs_Template, and LR Procedures.

Table 1
Original Label Review Policies Manual Composition

Original Label Review Policies and Procedures Manual Composition		
Sections	**Amount**	**Percentage**
Administrative	34	26.8%
LR Product Review	1	0.8%
Emails	42	33.1%
Focus Sessions, SR, and other Training	10	7.9%
In-Progress Label Review Procedures	40	31.5%
Total	128	

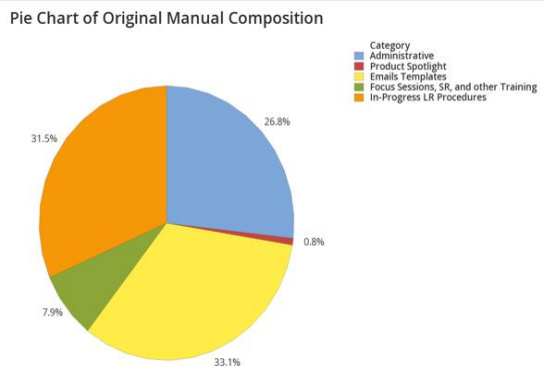


Figure 1
Pie Chart of Original Label Review Policies and Procedures Manual Composition

As shown in Figure 1, the Emails section is the biggest section in the original Label Review Policies and Procedures Manual with a 33.1%. For the Administrative section, the focus was to focus on department and HR related information. The proposed administrative section organization contains a total of 17 documents. Compared to the original organization, the section size was reduced by 16 documents representing an approximately 48% reduction. The Product Review section was renamed and repurposed to the Product Spotlight. The Product Spotlight is an opportunity for a Label Reviewer on showcasing any unique, rare, and interesting product with other Label Reviewers. This section's focus is to work as an archive for product spotlights done every first Tuesday of each month. To standardize this section, the Product Spotlight Guide was created to provide a template for any Label Reviewer to use to create their own creative version. The Focus Sessions, SR, and Training section was converted into the Training Section divided into the following 12 subpages: Tutorial & LR Tips, Food, Dietary Supplement, Detention, Cosmetic, FCS, Medical Devices, Color Additives, Drugs & OTC, TTB-Alcohol, Animal Feed and Focus Sessions. This section focus was to create standardized, updated, optimized and organized location for any Label Reviewer to have access to training tools and relevant information needed based on the product category. The Tutorials & LR Tips subsection was created to provide guidance to any new and/or current Label Reviewers in a visual friendly manner for daily tasks such as Excel Nutrition Calculator, how to register personal time off (PTO), among others. Throughout the other 11 subsections, the 5s philosophy was implemented in order to establish Label Review friendly visual organization. For the Email Templates and Email Blurbs category sections, it was determined that the best use of the Lean Six Sigma Methodology and 5s Philosophy was to merge the sections into the Email_Blurbs_Templates. This section provides a copy-paste friendly and alphabetically sorted to allow Label Reviewers to easily find the needed templates and reference examples blurbs. The templates and references examples are identified as the following: the templates have a white background and reference only examples have a red background with a header in Caps Lock. In the other hand, the In-Progress LR Procedures was renamed to LR Procedures and updated standard operating procedures to reflect the Label Reviewer daily work

in a remote environment. As shown on Table 2, the new proposed Label Review Policies and Procedures Manual composition contains a total of 429 files. The Training Section increased approximately 30 times more compared to the original manual directly impacting the Training Department. As shown on Figure 2, the Training section represents a 73.3% of the proposed Label Review Policies and Procedures Manual. On the other hand, the LR Procedures reduced in an 80 % compared with the original manual.

Table 2
The Proposed Label Review Policies and Procedures Manual Composition

Proposed Label Review Policies and Procedures Manual Composition		
Sections	**Amount**	**Percentage**
Administrative	17	4.0%
Product Spotlight	2	0.5%
Emails_Blurbs_Templates	88	20.5%
Training	315	73.3%
LR Procedures	8	1.9%
Total	429	

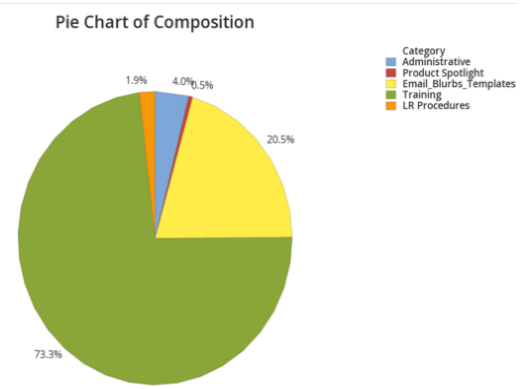


Figure 2
Pie Chart of the Proposed Label Review Policies and Procedures Manual Composition

The optimized cloud document sharing system could impact different departments such as the Training and Human Resources department by reducing workload and ensuring accessibility, standardization and increasing efficiency and productivity in documentation retrieval. Additionally, 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.

Table 3
Pre-Launch Individual Score Results

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%

As mentioned above, to determine the efficiency in documentation retrieval on the Label Review Policies and Procedures Manual, two assessments were created to establish how each Label Reviewer interacts with the original and the proposed Label Review Policies and Procedures. Therefore, the assessments were sent to Label Reviewers before and after the launch of the New Label Review Policies and Procedures Manual. The assessment consists of 12 total questions with the purpose to determine how much time each Label Reviewer takes to search and retrieve the requested documentation. The administered questions were yes or no multiple-choice direct questions.

As shown in Table 3, the average score of the pre-launch assessment is equivalent to 9.6 out of 12 questions (80%). The lowest score corresponds to Individual E with a 50% and highest score.

Corresponds to individual C and K indicating that Label Reviewers may not understand or know how to use appropriately the original Label Review Policies and Procedures Manual 9 out of 11 individuals had at least one incorrect answer in the assessment. A total of 8 individuals did not assert the correct answer for Questions #10. On the hand, Question #4, was asserted by all individuals.

Table 4

Pre-Launch Time Breakdown per Question

	Individuals Response (s)											
Assessment	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

As shown on Table 4, the highest time response average is for Question #1 and the lowest time response average is for Question #4. Individual F with an equivalent of 1045 seconds in total was the longest assessment time log response compared to the other individuals.

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%

Table 5

Post-Launch Individual Score Results

The new Label Review Policies and Procedures Manual launch was presented, discussed, trained, and explained thoroughly on August 31, 2022. Label Reviewers had the opportunity to navigate and to provide feedback for 2 weeks. Afterwards, the post-launch assessment was assigned and executed. As shown on Table 5, the post-launch average score is 10.9 out of 12 representing a 91%. The average score results increased 11% compared to the Pre-Launch Score Results. 5 out of 11 individuals got a perfect score. Additionally, 8 out of 11 individuals improved their original score compared to the Pre-Launch Score Results. However, Individual E remain the same score with a 50%. This result might indicate that would require additional time to adapt to the new spatial organization arrangement of the Label Review Policies and Procedures Manual.

Additionally, this result might represent that the individual E may need additional training to better understand the new manual. Individual K represents a score result decrease from 100% to 92%. This result may indicate that individual might have gotten confused, made an error or marked incorrectly. 5 out of 11 individuals got at least one incorrect answer in the post-LR assessment. It should be noted that there was a reduction from 9 to 5 individuals who got at least one incorrect answer in comparison with the Pre-Launch assessment.

As shown on Table 6, the average time response for Question 1 is 59.9 seconds with a standard deviation of 48.3s. 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. Question 3 average time response reduced from 56.9 s to 16.4 s representing a representing a 71% reduction.

Additionally, Question 11 average time response reduced from 46.5 seconds to 38.0 seconds representing a 18% reduction. In the other hand, Question 2,4, 5, 6, 7, 8, 9, 10 and 12 average time response from pre and post Launch increased. However, the productivity and score results (correct answer) increased. As shown in Table 5, Question 10 shows that only Individual E did not retrieve the correct documentation. The productivity of the overall documentation retrieval assessment in the post-Launch increased. As shown in Figure 3, the visual comparison between the pre-and post LR Launch Results demonstrate an improvement in the score result.

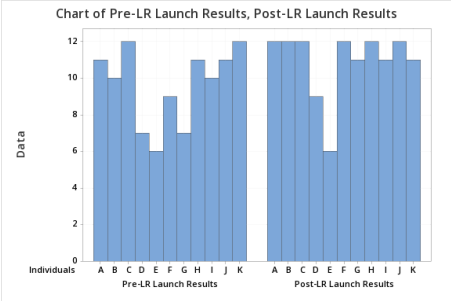


Figure 3
Bar Chart of Pre- and Post- Launch Score Results

The total time response average is 472.3 seconds in Table 6. The One-Way ANOVA was executed to compare the total times per individuals in each assessment and to determine the efficiency of the new Label Review Policies and Procedures Manual. The null hypothesis states all means are equal. The alternative hypothesis states not all means are equal. The significance level (alpha level) is 0.05 with a 95 % Confidence Interval. The p-value is 0.436 representing that p-value is the greater than (>) α which means there is not enough evidence to reject the null hypothesis that the population means are all equal.

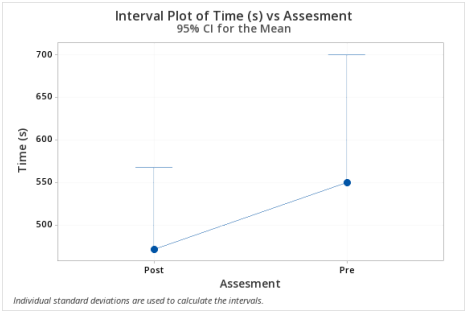
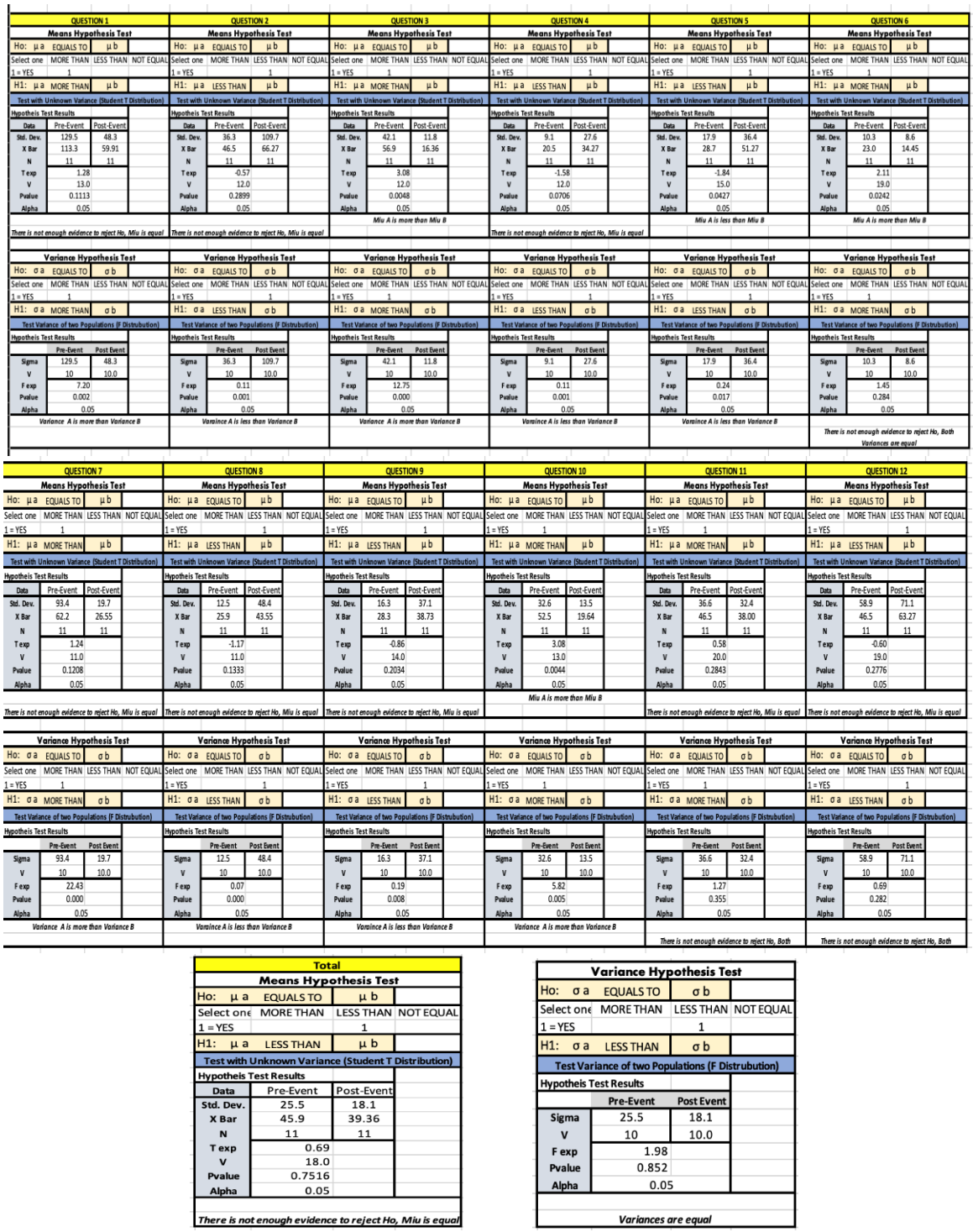


Figure 4
One-way ANOVA: Interval Plot of Time (s) versus Assessment

As shown on Figure 4, the average total time of the Post Launch Results are less than the Pre-Launch Results. The difference of the average total time between Post Launch Results and Pre-Launch Results is 78.4 seconds. The time reduction percentage of the new Label Review Policies and Procedures is determined by dividing the average total time of the Post Launch Results with the average total time of the Pre-Launch Results and subtracting with 100%. The time reduction percentage is equivalent to approximately 14.3%. The mean and variance hypothesis test were executed for each question individual's time response.

Table 6
Post-Launch Time Breakdown per Question

	Individuals Response (s)											
Assessment	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	46	249	40	25	54	39	17	63.3
Total time	412	328	358	452	474	898	433	267	665	388	520	472.3



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			

Figure 5

Mean and Variance Hypothesis Test per Question and Total Average Time

The comparison of the Pre and Post Launch means and variances was executed by performing a hypothesis test. The significance level (alpha level) is 0.05 with a 95 % Confidence Interval. As shown in Figure 5, the Post-Launch mean is lower than the Pre-Launch mean in the Questions 1, 3, 6, 7, 10, and 11. In the other hand, the post-Launch mean is greater than the Pre-Launch mean in the Questions 2, 4, 5, 8, 9 and 12. The null hypothesis for each question is that the Pre-Launch mean, and post-

Launch is equal. However, the alternate hypothesis is not the same for all questions. For questions 2, 4, 5, 8, 9 and 12, the alternate hypothesis is that the Pre-Launch mean is less than post-Launch mean. For Questions 1,3, 6, 7, 8, 9, 10 and 11. To determine the efficiency on each question and specific documentation retrieval, the p-value will be compared with the alpha level. 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. 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. Regarding the variances hypothesis, Question 1, 3, 7, and 10 establishes that the Post-Launch variance is significantly less than the Pre-Launch representing less variability within the documentation retrieval between staff members. On the hand, Questions 2 ,4 ,5 ,7 ,8 and 9 the Post-Launch variance is significantly more than the Pre-Launch variances representing that the new Label Review Policies and Procedures increased the time variability between staff members. For Questions 11 and 12, the hypothesis null is not rejected indicating that both variances are equal. However, 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 hypothesis test for the total average time establishes that the p-value is greater than (>) the α which means there is not enough evidence to reject the null hypothesis and both Pre-and Post- Launch are equal. This result establishes that the 14.3% represent that the Post-Launch total time average is not significantly less than the Pre-Launch as the p-value is more than α. Additionally, the variance hypothesis test determined that both Pre and Post Launch variances are equal because the p-value is greater (>) than the α indicating that the individuals time responses have a high variability.

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. The high variability between staff members time response represents the need of a retraining and follow up assessment to determine if the Label Review Policies and Procedures can significantly reduce the time of documentation retrieval. Additionally, the significantly high variability time response can also bring insight on the level of the technological skills of staff members. The results propel a detailed investigation to determine the factors that may have caused the increased variability of each question. Therefore, a review and analysis will be performed to establish the required improvements to strengthen the Label Review Policies and Procedures Manual.

CONCLUSIONS

The new Label Review Policies and Procedures manual increased the productivity, efficiency, and accessibility. The problem stated 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 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. If individuals had more time getting to know the new Policies and Procedures Manual before the assessments, the results may differ to demonstrate significant documentation retrieval. By increasing the efficiency, the customer satisfaction will increase causing higher revenue and possible higher customer referrals. The new launched manual will provide more accessibility, standardization, process stability and understanding within the department. The Training Section provides a new opportunity for current and potential new Label Reviewers to be up to date regarding different categories within the organization. This section will directly impact the Training Department by making Training process to be an internal,

detailed-oriented department training with actual information and tools that reflect the current daily tasks and process flow. Additionally, 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. The Administrative section of the manual provides the updated and current Human Resources related documentation that will be in a click away access allowing Label Reviewers to avoid management chain issues. Additionally, a quality documentation tracking system was implemented in order to implement the continuous improvement and to start the development of the Quality department. The launch of the new Label Review Policies and Procedures Manual is used as project pilot for other departments in order to be able to improve department's daily task. The project represents the start of the measurement of quality parameters in the organization. The next future step for this project is to perform a review and analysis to determine the factors affecting the time responses of each Label Reviewer per question. Additionally, follow-up assessment will be administered to determine if the time documentation retrieval reduction was significant or not. In order, to achieve a significant time reduction, detailed retraining and follow-ups weekly exercises will be executed. Consequently, a qualitative survey will be conducted to provide insight on how Label Reviewers feel about the new manual. As part of the quality incorporation wave, the Label Review will start quality audits every 3 months to ensure that the new Label Review Policies and Procedures is optimized and updated.

REFERENCES

[1] House of Representatives, Congress. (2010, December 30). *21 U.S.C. 321-Definitions;* generally. [Government]. U.S. Government Publishing Office. [Online] Available: https://www.govinfo.gov/app/details/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapII-sec321/summary

[2] *Learn more about a SaaS Cloud EDMS that helps to manage business growth and the profusion of files that come with it.* eQuorum. (2022). [Online]. Available: https://www.equorum.com/resources/what-is-a-cloud-document-management-system

[3] J. M. Juran and A. B. Godfrey, *Juran's Quality Handbook*. New York: McGraw Hill, 1999.