

5S as a Lean Tool in a Validation Laboratory in Puerto Rico

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Abstract — *The target of this study was to investigate the application of the 5S improvement methodology in a Validation laboratory to determine the impact on test efficiency. The investigation was conducted using a single-case study approach in a Validation laboratory. Quantitative data was analyzed using statistical analysis tools for BCT test times per process step and laboratory technician before and after implementing the 5S. Qualitative data were gathered from the workforce through questionnaires before and after the tool's implementation. The study substantially improved laboratory test efficiency and employee engagement after applying 5S. Overall, test efficiency increased to 86.4% after the implementation of 5S. This investigation provides additional literature on the efficiency improvement process in a laboratory setting using the 5S improvement method. Future studies should utilize a bigger sample size or extend the multiple areas to increase the reliability of the findings.*

Keywords — *5S, Improvement, Laboratory, Test Efficiency.*

INTRODUCTION

An essential and key part of the manufacturing industry are laboratory assays. Laboratory assays in many instances determine product quality and integrity, including the incoming raw material, during the assembly or product of the goods and during the final stages of the production process. The execution of laboratory assays is a key practice which depends and is based on scientific evidence to detect areas of opportunity for a determine product or service [1]. Currently, Laboratory ST is dedicated to cartridge filter validations, the main service performed by this laboratory include viability (VT) and bacterial challenge test (BCT). No lean

processes are performed within this laboratory. Test turnover is high due to an unorganized laboratory, where technicians take approximately two hours searching for test materials throughout the laboratory. Laboratory lean management tools have proved to increase test efficiency and reduce technician fatigue.

The concept of Lean Laboratory Organization is originated on the concept of Lean Thinking, which started after World War II in Japan with the Toyota Production System [2]. The intention of lean thinking is the elimination of waste in a production system or service. In this paper the term *value* refers to the capability of Laboratory ST to produce a validation project for the intended customer upon the requested time and within a reasonable or agreed cost. Studies have discussed that currently there are eight (8) types of non-value activities [3] [4].

Research Objective

The main objective in this research is increase test efficiency in the Laboratory ST by implementing 5S technique in the area. Currently, the laboratory does not have 5S in place. Also, develop a standardized checklist that the technicians can use to evaluate the workplace organization to sustain the 5S program. Furthermore, assess if all the materials and equipment that are currently in the Laboratory are adequate for performing the VT and BCT.

Research Contributions

This investigation will contribute to the studies and literature on utilizing the 5S improvement tool in a laboratory setting. It will also provide a documented scientific approach and evaluation that Laboratory ST will eliminate waste in the form of motion by using the 5S methodology. Furthermore, this investigation will contribute to reducing Validation laboratory analyst workload at least 15%

after implementing the 5S organization technique in the laboratory.

LITERATURE REVIEW

It is common that many consider the 5S as only a mechanism for cleaning. However, in a magazine article written in 2006, Van Pattern demonstrates that the 5S system can be useful for improving overall production numbers. In this article, one business used the 5S system to organize a warehouse and evaluate which final product moved slower than others and the reasons why the product was not being shipped [5]. This lean technique derives from the following Japanese terms: *Seiri*, *Seiton*, *Seiso*, *Seiketsu* and *Shitsuke*.

The English translation of the five Japanese terms is sort, set in order, shine, standardize, and sustain, respectively. In the 5S approach the term sort will refer to the elimination of anything that is not required for a particular process or test. After removing the elements that are not required in the area, the remaining elements must be set in order or organized. In other words, everything must have an assigned and identified place. After the set-in order step proceeds the shining aspect of the discipline. This step can be interpreted in two different ways. For example, many understand that it refers to cleaning the production areas and identifying the sources of dirt. While it can also mean to gather and process information to pinpoint the root cause of the dirt, which is a form of waste. Next is to standardize the key processes and the organization's approach. In other words, the goal of the standardization phase is to establish the rules for keeping up with the first three steps. Finally, the most challenging step for many organizations is sustaining the implemented approach or improvement. In this last step, a mechanism must be developed to oversee the system [2][4] [5] [6].

Lean management tools are not limited to the 5S approach. Other terms for process improvement in Laboratory scenarios can be seen using the Six Sigma concept which is also considered as a lean technique of process improvement. Take for instance

a clinical pathology laboratory that used the Six Sigma approach to improve the management and handling of reagents. The primary emphasis of this improvement project was to study the precision and accuracy of the system that the Clinical Pathology Laboratory has in place. This laboratory referred to the Six Sigma method as a statistical method employed for the reduction of variations in the process of interest, aiding in the reduction of cost in the production environment and services, focusing on savings and customer satisfaction [7].

More than an organization approach, the 5S method can also be used to promote a safe work environment. The main areas of improvement will include an organized work area and a safe workstation. Furthermore, many studies consider the 5S to be the first step toward a company becoming Lean [8]. Mainly assigning a specific place for everything and executing the sorting phase, safety will be a default outcome of those two actions.

Likewise, in Bogotá, Colombia, a study was performed to evaluate the potential the 5S approach would have in a manufacturing area. At the end of the study the outcome of the study demonstrated a positive relationship with the implementation of the 5S and an increase in productivity and quality. The study also yielded positive performance metrics, an improvement of business culture, and a reduction of risks [9].

Literature studies have demonstrated that companies can fail in the attempt to create a lean environment. A study performed in the United Kingdom (UK), took into consideration that the failure of many businesses is due to the incorrect order of the crucial tools used in the lean approach. The evaluation of the order of implementation was key to the success of the UK-based company [10].

Lean tools can be used in a variety of scenarios, from manufacturing areas to laboratories. A microbiology laboratory in Serbia was confronting loss in capital, increasing volumes, and workforce absences, and with the concepts discussed, the microbiology laboratory used Six Sigma concepts and methods to automate processes and consequently increase laboratory efficiency. In the

implementation of the method, four wasteful activities were highlighted and posteriorly eliminated. Overall, the eliminated processes were those with high dispersion, test variability was condensed, and the test turnaround time was also reduced [11].

METHODOLOGY

This study evaluates the impact of implementing the 5S improvement tool in Laboratory ST. The focus was to evaluate the current state for test efficiency of the laboratory before the implementation of the 5's and after the application of the tool. A single study method was executed to simplify observation and evaluation. The study was executed in a filter validation laboratory of a medical device company.

Throughout the study both qualitative and quantitative data was gathered. Overall, eight laboratory employees with background in Science, Biology and Microbiology participated in the study. The quantitative component of the study consisted of the evaluation of the turnaround time of the eight technicians during the execution of the BCT. While the qualitative approach of the study consisted in interviewing the technicians' gathering data about perceptions and knowledge of the improvement tool before and after the implementation of the 5S.

Based on the literature review, used for this project a standardized checklist was developed for laboratory ST. The assessment of the materials will be performed mainly by following the first three 5s of the approach. Lastly, an evaluation of the time the technicians take to gather the materials for each test before implementing 5S and after implementing the project. With these values estimate the time saved with the implementation of the lean approach.

RESULTS AND DISCUSSION

Two different categories of research were executed in the study: quantitative and qualitative research.

The first step in the qualitative research was to understand the insights of the workforce of

Laboratory ST and the 5S improvement tool. For example, each employee was interviewed related to the topic. At the time the research was conducted, the composition of the workforce of the Laboratory consisted of eight laboratory technicians, once administrative assistant, one laboratory manager, one quality manager and one regional validation manager. An 83% (10/12) of the team, mainly the eight laboratory technicians, the administrative assistant and the regional validation manager had no related experience in with the 5S topic or lean processes. Whereas a 17% (2/12) of the team, the laboratory and quality managers, understood the concept from previous professional experiences. All laboratory activities were overseen and audited by the quality manager to guarantee regulatory compliance.

With this information, training (educational) sessions to the 83% of the team were conducted in the Laboratory ST to widely discuss and educate in 5S improvement method. The discussion focused on the origins of the 5S and the important benefits of its application in a laboratory setting, incorporating the need of discipline among the laboratory employees to sustain the incorporated changes.

Before the implementation of the 5S activities, an assessment of the ST Laboratory layout was executed through direct observation. The observations yielded several issues, including defective or broken equipment, a cluttered layout resulting in movement waste (excessive travel distances) and consequently extensive test turnaround time and poor efficiency.

After the qualitative approach of the research was executed, the quantitative section of the study was started. For example, before the implementation of the 5S in the laboratory and after all personnel were educated, the BCT and VT tests were evaluated for each of the eight laboratory technicians. Every technician gathered all the materials to perform the test while each key step was timed with a chronometer. The steps that were analyzed are detailed as follows:

1. Time elapsed during the selection of the transportation buggy.

2. The time it took each technician to collect the parts for the sterilization of the BCT Rig.
3. How long it took to select to disinfecting agents to sanitize the laminar flow hood (LFH).
4. Time elapsed in the retrieval of the culture that would be used for the test.
5. Disinfecting time of the LFH.
6. The selection of tweezers, metal scissors, clamps and hoses.
7. Locate the stopwatch.
8. The assembly of the BCT rig.
9. Gathering of the stock culture.

Table 1 shows variability among the eight technicians while preparing for the analyzed tests. The least of time a technician took to prepare for the execution of the tests was 103 minutes while the longest time elapsed among the technicians was 125 minutes for two technicians. However, evaluating the data, two of the steps showed the same standard time for all the technicians. The two steps were the retrieving of the cell culture media and the retrieval of the test stock culture, both steps took all the analysts 5 minutes for each step. The cell culture media were in a cold room where all media was identified and color coded, making the selection of the required media quick and easy. This same concept was applicable to the stock culture, the stock cultures were in an industrial refrigerator next to the cold room. Just as with the cell culture media, the stock cultures were identified and color coded also making their identification and retrieval quick and easy. The step that took the longest to execute was the gathering of the BCT parts for the sterilization cycle processing. This specific process required the technicians to search for all the parts required for the BCT rig, these were not located in a specific place rather than throughout the entire laboratory. Figure 1 shows that step 2 (The time it took each technician to collect the parts for the sterilization of the BCT Rig) was had the longest execution time. Furthermore, the technicians did not have a specific document that guided them with the quantity needed of each part. The longest time elapsed for this process step was 48 minutes for technician D. The

other process steps had the same analogy, the parts were located throughout the entire laboratory space rather than in a specific identified location. Also, Figure 2 shows a detailed summary per technician's execution time. The average time the technicians took to execute the nine BCT steps was 116.5 minutes.

Table 1
BCT /VT Step Analysis Before the Implementation of 5S

BEFORE	TECHNICIAN							
	A	B	C	D	E	F	G	H
1	10	9	11	10	8	10	7	7
2	45	40	39	48	38	41	39	39
3	8	9	10	9	8	7	7	9
4	5	5	5	5	5	5	5	5
5	8	6	6	6	6	6	6	6
6	18	19	15	14	18	11	15	14
7	6	7	4	7	6	8	5	6
8	22	19	20	21	17	21	19	22
9	5	5	5	5	5	5	5	5
TOTAL	127	119	115	125	111	114	108	113

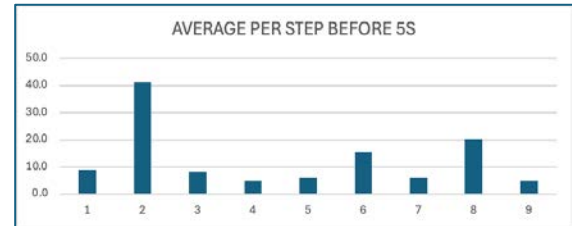


Figure 1
Average Time per Step Before the Implementation of the 5S Methodology

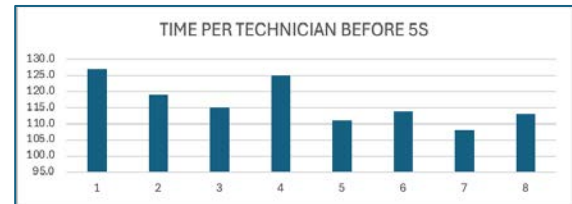


Figure 2
Average Time per Technician Before the Implementation of the 5S Methodology

The average samples received in laboratory ST for BCT and VT testing for one week (7 days) was 22 samples. Before the implementation of the 5S approach only 8 tests out of 22 were completed without delay. To calculate the efficiency of test before the implementation of the 5S the equation listed below was used.

$$\text{Test efficiency} = \left(\frac{\text{Total number of BCT completed}}{\text{total number of BCT received at the laboratory}} \right) \quad (1)$$

$$\text{Test efficiency} = (8/22) (100) = 36.4\%$$

With the aforementioned information the test efficiency/completion of the Validation Lab ST before the implementation of the 5S was 36.4%. This information triggered Laboratory management to give top priority to the implementation of the improvement method and create a standard for measuring the result of the implemented approach.

After the data results of the efficiency were calculated, the laboratory technicians were divided in two groups. The first group, which included four technicians, and the laboratory manager, were accountable of the “Sorting” (*Seiri*) process of the equipment and instruments in the laboratory. In this stage, the group evaluated the condition of each material, the instruments that were deemed defective or worn were identified with red tape and removed from the area. Also, equipment that belonged to other areas or departments were removed and returned to the owners. Reagents, including liquids, solids, bases and acids were examined for expiry dates; expired reagents were also flag with the red tape and properly discarded following local policy.

After the first group concluded the task, the second group composed of the other four technicians alongside of the laboratory assistant, moved on to the next step of the 5S methodology, the organizing or “Set in Order” (*Seiton*) phase. The focus in that phase was methodically organizing and labelling equipment according to category and functionality. Color coded marking adhesive and labels were employed to define storage places. Yellow adhesive identified specific places where the equipment was placed, blue adhesive was used for walkways and red adhesive for biohazard disposal areas. All the materials that were retained from the sorting phase then were organized in a manner that the technicians could have easy access to them while executing the BCT and VT tests. For example, each BCT station and LFH were equipped with a small cabinet next to the station where every material had a specific place assigned and properly labeled. All the cabinets were configured in the same exact way. The only materials that were excluded from those cabinets

were the media and stock solutions because due to temperature storage requirements. However, as mentioned in the previous section, the refrigerator and cold rooms were already organized in a way where every material had its specific location and were color coded. Furthermore, locations for dirty equipment, equipment pending sterilization and spare parts had assigned designated areas.

The “Shine” (*Seiso*) in this improvement focused on the importance of hygiene and the correct functionality of the instruments within the ST laboratory. For this step, the 8 technicians, administrative assistant and the Laboratory manager worked to deep clean the laboratory and determined frequency of cleaning moving forward after the implementation. For instance, cleaning and sterilization of instruments was performed per use, but floor, walls and adjacent counter tops were determined to be cleaned weekly. These cleanings were initially audited by the quality manager. Overall, the cleaning schedules were developed and included in local policies. Along with the cleaning schedules, internal maintenance schedules were also developed in this phase for those instruments that did not have them. Consistent maintenance and cleaning of the instruments not only contributed to visual appearance of the laboratory ST nonetheless also promoted safety and guaranteed optimal functionality of all the laboratory instruments.

After the third S (*Shine*) was deployed in the laboratory, the BCT and VT test were evaluated again for each of the eight laboratory technicians.

Analyzing the data after the implementation of the three S, just as in the initial analysis, the step that took the longest to execute was the gathering of the BCT parts for the sterilization cycle processing. During this evaluation, the gathering of the BCT parts took a shorter period. For example, during initial evaluation of this process step, the worst case was 45 minutes. Contrary, to the evaluation performed posterior the implementation of the 5S approach, where the worst case was 15 minutes. Refer to Table 2 for the step analysis after the implementation of 5S. Figure 3 shows the detailed times per process step after the implementation of 5S

in the ST Laboratory. Moreover, all the process steps shortened their execution time. Also, Figure 4 illustrates the average time it took each technician to complete the nine steps of the BCT process. Each technician showed a reduction in execution time for the test. Subsequently, with these improvements, 19 out of 22 BCT/VT were completed without delay. The three that could not be completed were pending information from the respective clients regarding execution strategy of the test. The calculated test efficiency after the implementation of the 5S approach was 86.4%.

Table 2
BCT /VT Step Analysis After the Implementation of 5S Methodology

STEP	TECHNICIAN							
	A	B	C	D	E	F	G	H
1	5	4	5	3	5	5	4	4
2	15	12	5	11	11	11	12	11
3	5	5	5	5	5	5	3	5
4	5	5	5	5	5	5	5	5
5	6	6	6	6	6	6	6	6
6	5	7	3	6	5	4	6	6
7	2	2	2	2	2	3	3	3
8	15	18	14	15	17	18	17	16
9	5	5	5	5	5	5	5	5
TOTAL	63	64	50	58	61	62	61	61

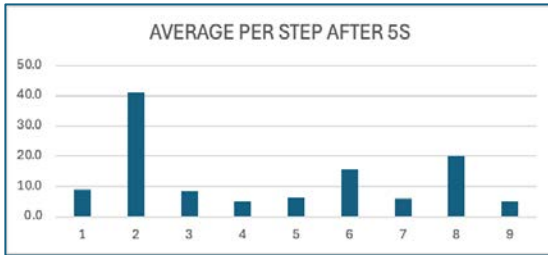


Figure 3
Average Time per Step After the Implementation of the 5S Methodology

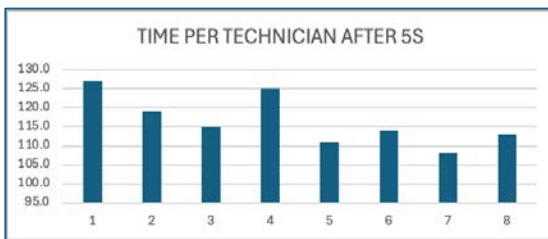


Figure 4
Average Time per Technician After the Implementation of the 5S Methodology

An analysis of variance was conducted to assess whether significant differences existed in technician execution before and after the implementation of the 5S in the laboratory. Using a one-way ANOVA, with a p-value of 1.0000 (> 0.05), shows that there was no

significant difference between the eight technicians, indicating that they all work in a similar manner. Refer to figure 5 and figure 6 for the ANOVA output and graphical representation.

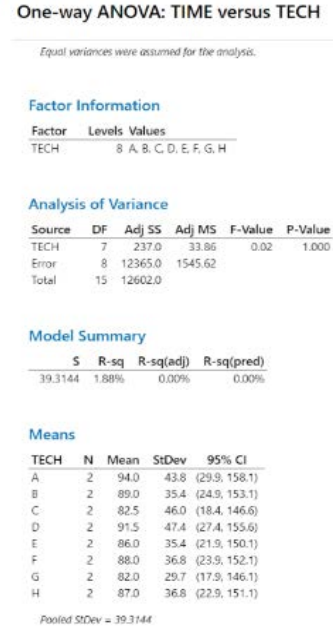


Figure 5
Analysis of Variance (ANOVA) Output Evaluation per Technicians

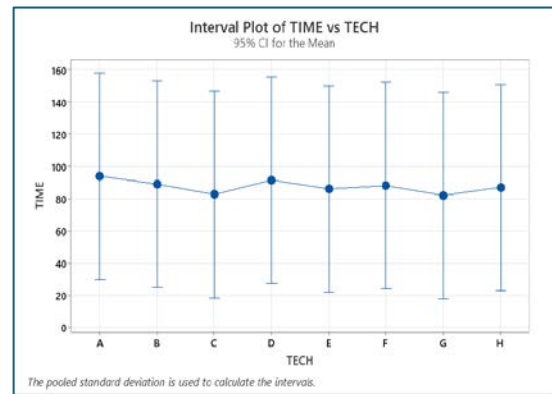


Figure 6
Analysis of Variance (ANOVA) Evaluation per Technicians Graph

Additionally, a mean hypothesis test was performed to assess if the implementation of the 5S in the ST Laboratory was statically significant. The null hypothesis stated that the average before 5S application was greater than the average after the application of the 5S ($\mu_a > \mu_b$), while the alternative hypothesis proposed that that the average before the

implementation of the 5S was not greater than the average after the implementation of the 5S ($\mu_a \leq \mu_b$). The results produced showed that μ_a (115 min) was greater than μ_b (60 min), therefore, the implemented improvements in the Laboratory yield a higher test efficiency and reduces waste in the form of waiting and movement. Refer to Figure 7 for the mean hypothesis test.

Mean Hypothesis Test Before and After Implementation			
BEFORE		AFTER	
TECH	TIME	TECH	TIME
A	125	A	63
B	114	B	64
C	115	C	50
D	125	D	58
E	111	E	61
F	114	F	62
G	103	G	61
H	113	H	61

Hypothesis			
H0:	μ_a	EQUALS TO	μ_b
Select one	MORE THAN	LESS THAN	NOT EQUAL
1 = YES	1		
H1:	μ_a	MORE THAN	μ_b

Test with Unknown Variance (Student T Distribution)			
Hypothesis Test Results			
Miu	115.00	60.00	
Std. Dev.	7.2	4.4	
X Bar	115.0	60.00	
N	8	8	
T exp	18.37		
V	12.0		
Pvalue	0.0000		
Alpha	0.05		
Miu A is more than Miu B			

Figure 7
Mean Hypothesis Test Before and After the Implementation of 5S

Variance Hypothesis Test Before and After Implementation			
BEFORE		AFTER	
TECH	TIME	TECH	TIME
A	125	A	63
B	114	B	64
C	115	C	50
D	125	D	58
E	111	E	61
F	114	F	62
G	103	G	61
H	113	H	61

Hypothesis			
H0:	σ_a	EQUALS TO	σ_b
Select one	MORE THAN	LESS THAN	NOT EQUAL
1 = YES	1		
H1:	σ_a	MORE THAN	σ_b

Test Variance of two Populations (F Distribution)			
Hypothesis Test Results			
	A	B	
Sigma	7.2309	4.4078	
V	7	7	
F exp	2.69		
Pvalue	0.107		
Alpha	0.05		
There is not enough evidence to reject Ho, Both Variances are equal			

Figure 8
Variance Hypothesis Test Before and After the Implementation of 5S

Meanwhile, a variance hypothesis test was also performed to evaluate consistency of the implementation. The variances before and after the implementation of the 5S produced the same information, which indicates that the process was consistent. Refer to Figure 8 for the variance hypothesis test.

The “Standardize” (*Seiketsu*) step of the 5S improvement in the ST laboratory concentrated in updating existing policies or developing new ones to address the finding of this study. As part of the standard operating procedure (SOP) of the BCT/VT tests, a new checklist was developed and issued to guarantee that the 5S are constantly being carried out and sustained. For example, each technician had to check off the list every material that was required for the test and after concluding the tests confirm that every instrument is placed at its assigned spot. The developed checklist also had a comments section to encourage the technicians to document any signs of wear and tear or additional issues encountered during the test. Furthermore, the technicians were included in the first fifteen minutes of the weekly laboratory staff meeting to encourage employee engagement to ensure that the 5S improvement contributed in a positive manner to the laboratory ST operations.

Finally, a critical aspect of the 5S methodology is the “Sustain” (*Shitsuke*) step, which concentrates on conserving the improvements within the ST laboratory. Each technician is accountable for their work benches, ensuring to maintain the work area per the implemented improvements. To sustain the implemented practices, the laboratory quality manager was authorized to conduct unannounced audits. The objective of the audits was to identify deviations from the established improvements, therefore promoting quick corrections to achieve a compliance state. Also, 5S continuing education was implemented to strengthen compliance and knowledge among the laboratory employees.

CONCLUSION

This study assessed the implementation of the improvement method 5S in a Validation Laboratory to evaluate the effect of the tool within the BCT process. The study was also addressed the ST Validation Laboratory high test turnover. Test turnover was decreased by increasing test efficiency and reducing technician fatigue due to an unorganized laboratory. Test efficiency prior to the execution of this project was 36.4%, whereas after the implementation of the project the calculated test efficiency was 86.4%. The reduction in BCT time execution improved the test efficiency of the laboratory and enhanced customer satisfaction. The time saved with the implementation of the 5S additional customer test can be executed. The methodology improvement in the laboratory also addresses employee morale, overall work culture and technician engagement. There was a positive increase in the work environment. Furthermore, the implementation of the 5S methodology paved the way for the development of a checklist every laboratory technician could reference to guarantee this approach is followed thru for other processes. Finally, continuous quality audits assured that this process was followed as established in the SOPs and ensure the continuous sustainability of the approach.

This project was limited only to the BCT and VT methodologies of the ST laboratory. Other test executed in the laboratory were not included as part of this project because BCT was considered as the test most of the ST laboratory clientele requested. Furthermore, although BCT and VT methods are considered microbiological test methods, the operational microbiology test methods were excluded from this study.

This project can pave the way of the ST laboratory to include the 5S methodology for the rest of the methods executed in the laboratory. Additionally, the work can be further developed in the operational microbiology laboratory to increase test efficiency.

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