Clean Room Space Optimization Through Lean-Driven Workstation Redesign and Financial Analysis

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Abstract: *A five-phase Lean methodology was implemented to improve space utilization in a medical device manufacturing cleanroom. The study concentrated on Zone A, comprising 25 workstations and 10 manufacturing processes. Application of 5S principles, workstation table redesign, and enhanced use of vertical space resulted in the release of 304 ft² of cleanroom floor space, representing a 35% reduction from the original 868 ft² baseline. Cycle time was reduced from 15,318 to 14,911 seconds, a statistically significant improvement of 407 seconds (paired t-test, t (9) = 4.48, p = 0.002). The I-MR control chart demonstrated consistent application of the methodology across workstations. Regression analysis indicated that original workstation size was a significant predictor of freed space (R^2 = 48.3%, p < 0.001). Financial analysis revealed strong economic value, with a net present value (NPV) of $446,568 and a payback period of 5.02 months.*

Keywords *— Cleanroom Optimization, Lean Manufacturing, Medical Device Manufacturing Space Utilization, Workstation Redesign.*

INTRODUCTION

The medical device industry operates under strict quality, efficiency, and regulatory requirements. Cleanrooms are essential to ensure product sterility and integrity, and their design has both technical and economic implications [1], [2], [3]. When a manufacturing facility decides to expand its product portfolio or integrate new processes, evaluating the existing space becomes a critical step before committing to costly construction projects [4].

This project addresses the challenge of optimizing the layout of a cleanroom in a medical device manufacturing facility in Puerto Rico. Due to accelerated business growth, the company needed to evaluate whether the existing space could be reorganized and released before considering physical expansion, given the high costs of construction and space maintenance in the industry. The study used a zone, referred to as "Zone A," as a reference. It contains 25 workstations and 10 manufacturing processes, with a total occupied area of 868 ft². To be clear from the start, validated manufacturing equipment with fixed dimensions was excluded from the redesign scope because its regulated nature limits the ability to streamline the change process. Instead, the focus was on the tables used by operators, which are easier to implement in the line.

The central research question was: Can a structured combination of the 5S methodology, workstation table redesign, and vertical space utilization achieve a measurable and statistically validated reduction in cleanroom floor space, supported by a positive financial case? This article presents the methodology, results, and conclusions of a project that successfully answered this question.

LITERATURE REVIEW

Cleanroom Design and Regulatory Context

Cleanrooms in medical device manufacturing must comply with ISO 14644-4:2022 for design, construction, and startup [1]. FDA 21 CFR Part 820 establishes production and process controls, providing a clear regulatory framework that supports the development of products aligned with high-quality standards [3]. The FDA recognizes ISO

14644-4 as a reference standard and requires facilities to provide adequate space to prevent mix-ups and ensure orderly product handling throughout the production line [5]. Beyond regulatory compliance, cleanrooms are resource-intensive environments; they can be 30 to 50 times more energy-intensive than average commercial buildings [6], making every improvement in space utilization financially and strategically relevant.

Facility Layout and Lean Manufacturing

Facility layout has a direct effect on productivity, material handling, and space utilization. The comprehensive review by Bouramtane et al. [7] identifies layout problems as among the most relevant topics in operations management and classifies them into static and dynamic categories. Applied studies that combine layout redesign with Lean tools have reported measurable improvements in production efficiency, reductions in travel time, and elimination of waste (Muda) [8], [9].

Among Lean tools, Value Stream Mapping (VSM) is widely used to visualize material and information flow and distinguish value-added activities [10]. The 5S methodology (Sort, Set in Order, Shine, Standardize, and Sustain) directly supports workplace organization and has been shown to reduce unnecessary movement and unproductive time in manufacturing environments [11]. The combination of VSM and 5S is particularly effective in linking macro-level process analysis to practical interventions at individual workstations [8].

Continuous Improvement in Regulated Environments

McGrane et al. [12] demonstrated that the regulatory environment in medical device manufacturing imposes significant barriers to Lean Six Sigma projects due to validation, documentation, and change-approval requirements. This confirms that improvement proposals in cleanrooms must be compatible with the quality system and change control processes. Naughton et al. [13] reinforced the importance of structured continuous improvement frameworks (such as PDCA, "Plan-Do-Check-Act") to sustain results over time. A research gap was identified in the practical integration of space optimization, Lean tools, and regulatory constraints in a single cleanroom project, precisely what this study addresses.

METHODOLOGY

The research followed an applied engineering design methodology with a quantitative approach, structured as a five-phase PDCA cycle [13]. The study was conducted in a single zone (Zone A) within a medical device manufacturing facility in Puerto Rico.

Phase 1: Current State Assessment

Each of the 25 workstations was measured individually to capture the following: total floor space before the redesign; occupied area on the table surface; occupied area within 2 feet above the table surface; and floor space required after the proposed configuration. A current-state VSM was developed from direct observations (Gemba walks) to document cycle times, WIP inventory, and non-value-added activities across the 10 manufacturing processes. The baseline cycle time was established at 15,318 seconds (4.26 hours), and Process 3 was identified as the dominant bottleneck, with 12,600 seconds (82.2% of the production line time).

Phase 2: Waste Identification and Analysis

The 5S methodology was applied systematically across the 25 workstations. "Sort" eliminated unnecessary items; "Set in Order" reorganized the remaining tools to minimize movement; "Shine" established cleaning standards aligned with ISO 14644-4 and FDA 21 CFR Part 820; "Standardize" documented the improved configurations; and "Sustain" defined audit criteria and visual controls [11]. A Kanban system was also designed to eliminate waiting waste caused by material shortages.

Phase 3: Workstation Redesign and Space Optimization

Each workstation was evaluated and redesigned according to strictly necessary operational criteria. The table dimensions were reduced accordingly, and items that were previously on the table and on the floor were relocated to the vertical zone, 2 feet above the table surface, using suspended bins, mounted monitors, and elevated supports [9]. Then, a future-state VSM was developed to document the improved flow, reduced cycle times, and elimination of waste.

Phase 4: Statistical Validation

Four statistical methods were applied using Minitab: (1) a paired t-test ($\alpha = 0.05$, two-tailed) to confirm the significance of the cycle time reduction; (2) two linear regression models to evaluate predictors of freed floor space; (3) a Pareto analysis to identify the highest-contributing workstations; and (4) an I-MR control chart to verify the consistent application of the methodology across the 25 workstations [14].

Phase 5: Financial Impact Analysis

The financial analysis quantified economic value through an avoided cost analysis (avoided additional construction cost at \$525/ft² and avoided recurring maintenance cost at \$275/ft²/year), payback period, NPV (at an 8% discount rate), IRR, and sensitivity analysis under pessimistic, base, and optimistic scenarios [15].

Results and Discussion

Space Optimization Results

The original Zone A layout occupied 868 ft² across 25 workstations. After the redesign, the required floor space was reduced to 564 ft², releasing 304 ft², a 35.0% reduction from the original area. This improvement was achieved by combining workstation table downsizing with the 5S application strategy, Kanban area optimization, and above-table vertical suspension, which allowed items previously stored on the table surface to be relocated 2 feet above the work surface. The production space value density improved by 53.9%, calculated as $(868 \div 564 - 1) \times 100$, meaning that each remaining square foot now supports a greater proportion of the original operation.

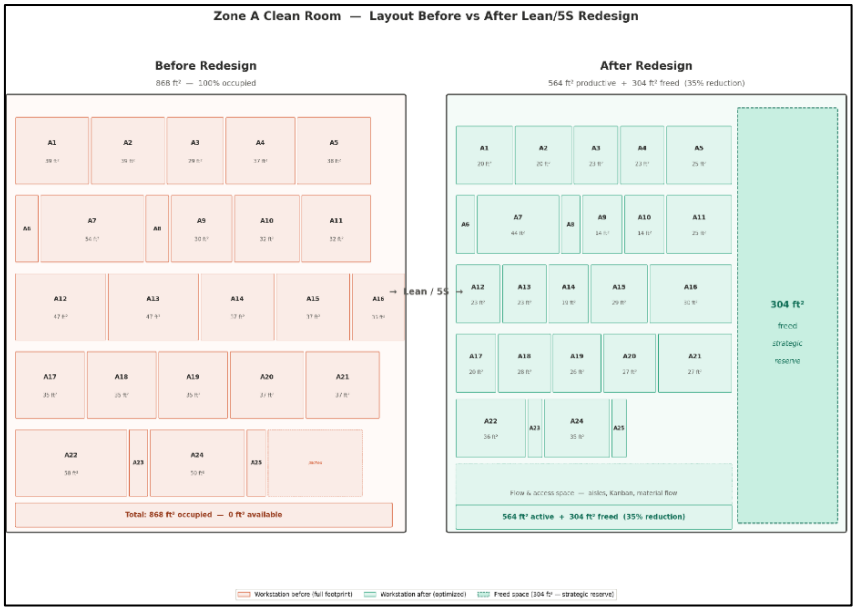

Figure 1
Comparison of Workstations Before, After, and the Released Space

Table 1
Space Optimization Summary – Zone A

Metric	Value
Original floor space	868 ft²
Post-redesign floor space	564 ft²
Released floor space	304 ft²
Reduction percentage	35.0%
Space value density improvement	53.9%
Workstations optimized	25

Cycle Time Reduction

Total line cycle time decreased from 15,318 seconds to 14,911 seconds, representing a reduction of 407 seconds (2.66%). The processes with the greatest percentage improvements were Process 2 (~14-15%), Process 4 (~13%), Process 10 (~13-14%), and Process 5 (12.73%). Although Process 3, the bottleneck, showed the smallest percentage improvement (0.87%), the 10 evaluated processes showed a positive difference between the before and after states, confirming that 5S and workstation reorganization reduced unnecessary movement and unproductive time, particularly in shorter processes [10], [11].

Table 2
Before vs. After Cycle Time Results

Cycle Time: Before vs After			
Process	**Before (seg)**	**After (seg)**	**Saving Time %**
1	258	246	4.65%
2	372	318	14.52%
3	12600	12490	0.87%
4	360	312	13.33%
5	330	288	12.73%
6	240	221	7.92%
7	468	426	8.97%
8	300	264	12.00%
9	120	112	6.67%
10	270	234	13.33%
Total	15318	14911	2.66%

Statistical Validation

The paired t-test yielded $t(9) = 4.48$, $p = 0.002$ ($\alpha = 0.05$), well below the significance threshold. The null hypothesis was rejected, confirming that the average cycle-time reduction of 40.70 seconds per process is statistically significant and not attributable to chance. The 95% confidence interval (20.13 s, 61.27 s) does not include zero [14].

Table 3
Paired t-Test Results – Cycle Time Reduction

Statistic	Value
N (processes)	10
Mean difference (Before − After)	40.70 s
95% Confidence Interval	(20.13 s, 61.27 s)
T-value	4.48
P-value	0.002
Decision	Reject H_0 (significant)

Graphical Analysis of Differences

Graphical analysis complemented the paired t-test by providing a visual assessment of the distribution, dispersion, central tendency, and potential outliers in the cycle-time differences. The histogram, value plot, and boxplot indicated that all 10 evaluated showed Before-After differences, confirming that none experienced an increase in cycle time after implementation. Most reductions clustered between 20 and 60 seconds, and the mean reduction of 40.70 seconds was clearly distinct from the null value of zero. The 95% confidence interval excluded zero, further reinforcing the statistical significance of the observed improvement [14].

Process 3 demonstrated the largest absolute reduction and appeared as a potential outlier in the graphical displays. This outcome was anticipated, as Process 3 was identified as the line bottleneck and had a substantially longer baseline cycle time than the other processes. Consequently, the presence of this outlier did not compromise the interpretation of the results. In summary, the graphical analysis confirmed that the cycle-time improvements were

consistent, positive, and supported the paired t-test findings.

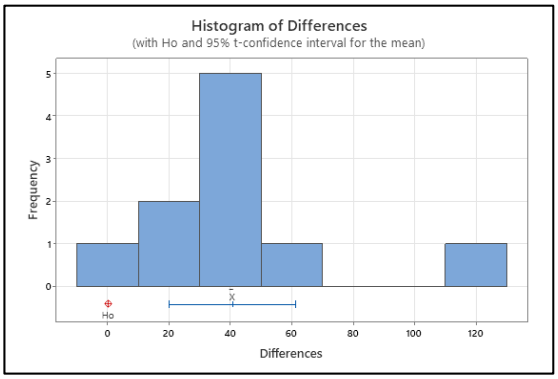

Figure 2
Histogram of Before - After Differences

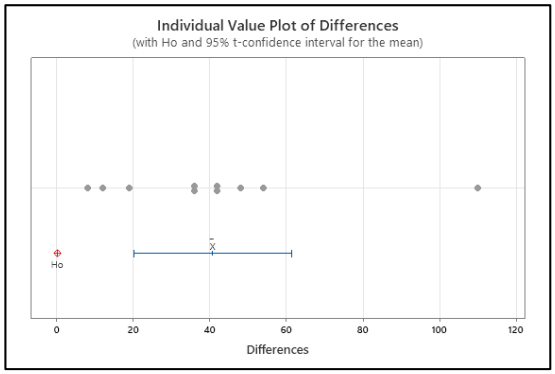

Figure 3
Individual Value Plot of Before - After Differences

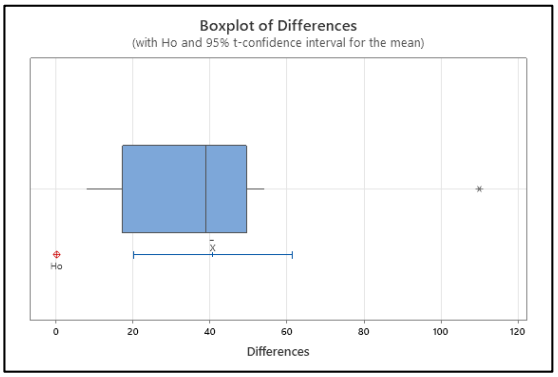

Figure 4
Boxplot of Before - After Differences

Linear regression confirmed that the original workstation footprint (before space) is a statistically significant predictor of freed space: $\beta_1 = 0.3705$, $F(1,23) = 21.47$, $p < 0.001$, $R^2 = 48.3\%$. For each additional ft² of original footprint, approximately 0.37 ft² was freed. A second model using the density of above-table suspended items was also significant ($p = 0.0174$, $R^2 = 22.2\%$), supporting the vertical suspension strategy as an important, although secondary, contributor. The combined model increased R^2 only marginally (49.0%), so Model 1 was selected as the most parsimonious [14].

The Pareto analysis revealed that 15 of the 25 workstations accounted for approximately 81% of the total 304 ft² released. The top five workstations (A13, A12, A22, A2, A1) released 113 ft², or 37% of the total impact, with only 20% of the workstations [14].

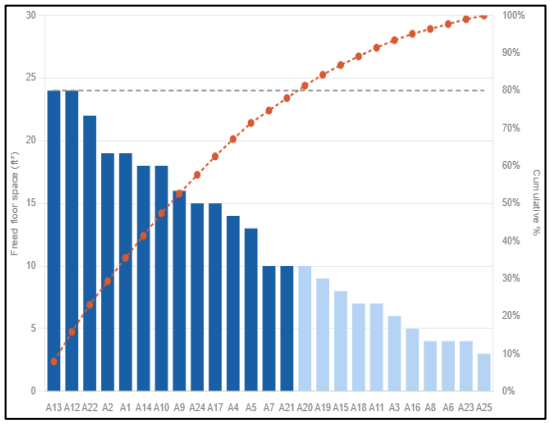

Figure 5
Pareto Analysis Graph

The I-MR control chart confirmed that the 25 data points fell within the control limits (UCL = 31.89 ft², LCL = 0.00 ft²), with no out-of-control signals in either the Individuals or Moving Range charts. The process was determined to be in statistical control, validating that the methodology was applied consistently and is reproducible across all workstations. This finding supports extending the same methodology to other zones of the facility, with confidence in the predictability of results [14].

Table 4
I-MR Control Chart Parameters

Parameter	Individuals Chart (I)	Moving Range Chart (MR)
Upper Control Limit (UCL)	31.8853 ft²	24.2304 ft²
Center Line (CL)	12.1600 ft²	7.4167 ft²
Lower Control Limit (LCL)	0.00 ft² (floored at 0)	0.00 ft²

Table 5
Summary of Key Statistics for the I-MR Control Chart

Metric	Value
Number of workstations (N)	25
Process means — Freed Space ($\bar{X}$)	12.1600 ft²
Mean Moving Range ($\bar{MR}$)	7.4167 ft²
UCL — Individuals Chart	31.8853 ft²
LCL — Individuals Chart	0.00 ft²
UCL — MR Chart	24.2304 ft²
LCL — MR Chart	0.00 ft²
Out-of-control points (I Chart)	0 of 25
Out-of-control points (MR Chart)	0 of 24
Process Status	**In statistical control**

FINANCIAL ANALYSIS

The financial analysis was conducted as an avoided-cost analysis. The 304 ft² released generated two avoided-cost components: avoided additional cleanroom construction cost ($525/ft² × 304 ft² = $159,600, one-time) and avoided annual cleanroom maintenance cost ($275/ft²/year × 304 ft² = $83,600/year, recurring). The total Year-1 avoided cost was $243,200, compared with a project investment of $35,000, generating a Year-1 Net Avoided Cost Value of $208,200 and a Benefit-Cost Ratio of 6.95. The spatial break-even point required only 44 ft² of released space to recover the investment [15].

Table 6
Financial Analysis Summary – Base Case

Metric	Value
Project investment	$35,000
Avoided construction cost (one-time)	$159,600
Annual maintenance avoidance	$83,600/yr
Year-1 total avoided cost	$243,200
Benefit-Cost Ratio	6.95×
Conservative payback period	5.02 months
NPV at 8% (5-year)	$446,568
IRR	632.6%

The conservative payback period (using only recurring avoided maintenance) was 5.02 months. If the avoided construction cost is recognized at the beginning of the project, the payback is considered immediate because $159,600 exceeds the $35,000 investment. The NPV at 8% over five years reached $446,568. The sensitivity analysis demonstrated robustness across all scenarios: the pessimistic scenario (250 ft² released, $400/ft²) produced an NPV of $332,091; the optimistic scenario (350 ft² released, $600/ft²) produced an NPV of $543,743. The analysis reinforced that the project creates economic value by avoiding potential costs and enabling operational capacity within the existing cleanroom [15].

Table 7
Sensitivity Analysis of Avoided Costs

Metric	Pessimistic	Base Case	Optimistic
ft² freed	250	304	350
Avoided construction cost/ft²	$400	$525	$600
Total Year-1 avoided cost	$168,750	$243,200	$306,250
Conservative payback	6.11 months	5.02 months	4.36 months
NPV at 8%	$332,091	$446,568	$543,743
Cost Avoidance ROI	3.82×	5.95×	7.75×

CONCLUSION

This project demonstrated that a structured five-phase methodology combining 5S, workstation table redesign, and vertical organization above the table can achieve significant and statistically validated space optimization in a regulated medical device manufacturing cleanroom. The following main findings were established:

1. Space reduction: 304 ft² (35%) released from a baseline of 868 ft², with a 53.9% improvement in production space value density, without additional cleanroom construction.

2. Cycle time: A statistically significant average reduction of 40.70 seconds per process was observed ($t(9) = 4.48$, $p = 0.002$) across 10 processes.
3. Reproducibility: The I-MR control chart confirmed that the methodology remained within statistical control across the 25 workstations, validating its extension to other cleanroom zones.
4. Predictability: The original workstation size is a significant predictor of freed space ($R^2 = 48.3\%$, $p < 0.001$); the above-table strategy is an important secondary driver.
5. Financial value: NPV of $446,568, Benefit-Cost Ratio of 6.95, and payback of 5.02 months, based on avoided costs.

The study had limitations: it was restricted to a single zone and facility; it would be beneficial to replicate this methodology in other zones and compare the impacts; the regression models explained less than half of the variation in freed space; and cost assumptions may vary across facilities. Future research should extend the methodology to other cleanroom zones, develop multivariate regression models with additional predictors, conduct longitudinal sustainability assessments, evaluate the ergonomic impacts of workstation redesign, and integrate discrete-event simulation to assess contamination risk and airflow effects.

The primary contribution of this research is an applied space-optimization framework that integrates workstation redesign, Lean-based waste reduction, statistical validation, and financial analysis in a regulated cleanroom environment. This framework demonstrates that significant operational and economic value can be achieved through systematic reorganization before committing to costly physical expansion.

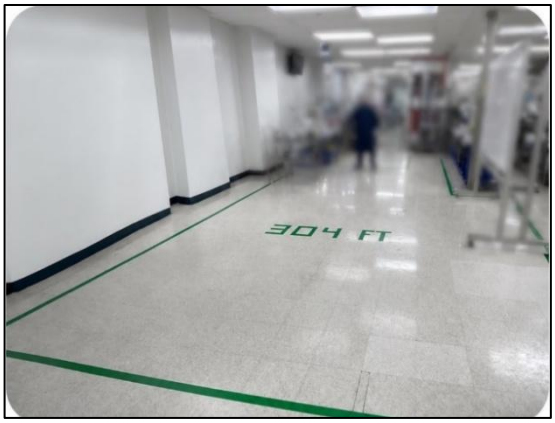

Figure 6
Photograph of the Released Space After the Redesign

Figure 7
Example of 5S Implementation with Vertical Arrangement

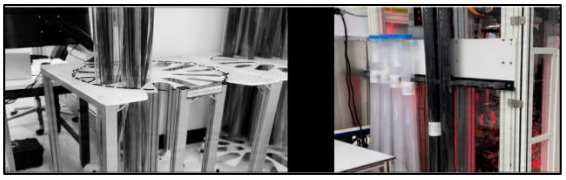

Figure 8
Example of WIP Optimization and Removal of Unnecessary Equipment

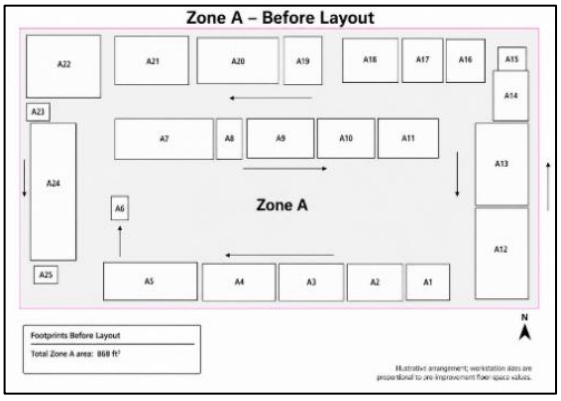

Figure 9
Previous Layout of Zone A

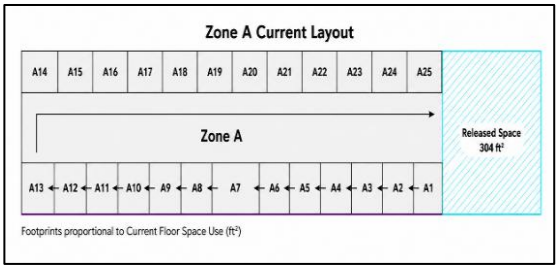

Figure 10
Redesigned Layout of Zone A

AI USE DISCLOSURE

This article used ChatGPT as a support tool for language refinement, grammar review, idea organization, formatting assistance, and translation. All interpretations, project data, statistical results, arguments, conclusions, and final decisions are the author's own and have been reviewed and verified for accuracy.

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