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

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Abstract

This project optimized space utilization in a medical device manufacturing cleanroom using a five-phase Lean-driven methodology focused on Zone A. The study evaluated 25 workstations and 10 manufacturing processes, excluding fixed validated equipment and redesigning only operator tables and storage. Through 5S, workstation table downsizing, Kanban area optimization, and vertical space utilization, the required floor area decreased from 868 ft² to 564 ft², freeing up 304 ft² (35%). Total line cycle time improved from 15,318 s to 14,911 s, and a paired t-test confirmed statistical significance, t (9) = 4.48, p = 0.002. Financial evaluation showed an NPV of $446,568, a BCR of 6.95, and a payback period of 5.02 months.

Introduction

Medical device cleanrooms must satisfy strict quality, sterility, and regulatory requirements while operating efficiently. When product demand grows, companies must determine whether existing cleanroom space can be reorganized before investing in expensive physical expansion.

Background

Cleanroom operations are governed by ISO 14644-4 and FDA quality system requirements, which emphasize adequate and orderly production space. Because cleanrooms are expensive to build and maintain, space optimization is both an operational and financial priority. Lean layout redesign, 5S, and Value Stream Mapping can improve flow, reduce waste, and increase space utilization.

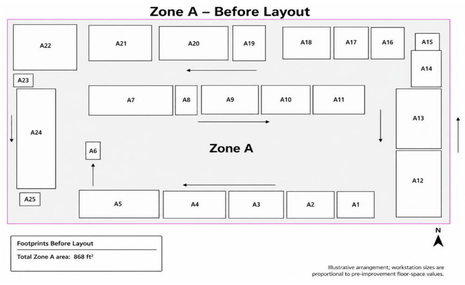
Problem

A medical device manufacturing facility in Puerto Rico needed to determine whether Zone A could be reorganized to create capacity before additional cleanroom construction. Zone A included 25 workstations and 10 processes occupying 868 ft². Research question: Can 5S, workstation redesign, and vertical space utilization achieve a measurable, statistically validated reduction in floor space while producing a positive financial case?

Methodology

1. **Measure current state**
   25 workstations, VSM, cycle time
2. **Identify waste**
   5S + Kanban material support [6]
3. **Redesign stations**
   Smaller tables + vertical storage [3]
4. **Validate statistically**
   t-test, regression, Pareto, I-MR [5]
5. **Analyze finances**
   Cost avoidance, NPV, IRR, payback

Previous Layout of Zone A



Before: 868 ft² footprint.

Results and Discussion

Redesigning Zone A reduced the required cleanroom space from 868 ft² to 564 ft², releasing 304 ft², or 35.0% of the original area. This change increased production space value density by 53.9% while preserving the same manufacturing operation. Cycle time decreased by 407 seconds, from 15,318 s to 14,911 s. A paired t-test confirmed that this reduction was statistically significant (t = 4.48, p = 0.002). Regression analysis indicated that larger workstation footprints provided greater opportunities for space reduction. Pareto analysis indicated that 15 workstations accounted for approximately 81% of the released space.

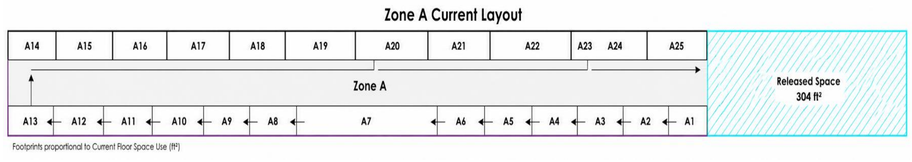
Space Optimization Summary – Zone A

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

Financial Analysis Summary – Base Case

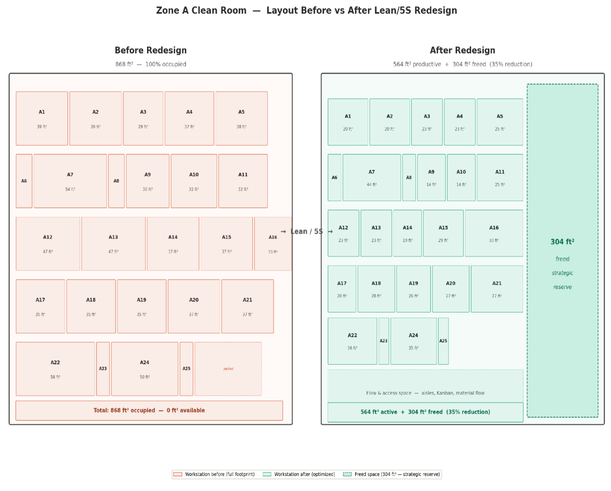
Project investment	$35,000
Avoided construction cost	$159,600
Annual maintenance avoidance	$83,600/yr
Year-1 avoided cost	**$243,200**
Benefit-Cost Ratio	**6.95×**
Payback period	**5.02 months**
NPV at 8% (5-year)	**$446,568**
IRR	**632.6%**

Zone A Current Layout with 304 ft² Released

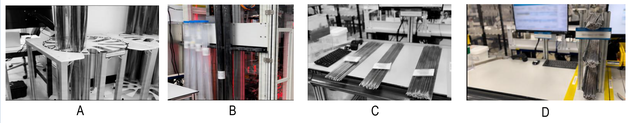


Current footprint = 564 ft²; released reserve area = 304 ft².

Space Distribution: Before vs. After



5S / Vertical Kanban Examples



A B C D

A. Before: Rotating rack for storing kanban cards, which was previously used to store work in progress.
B. After: Tube clamps to eliminate rotating racks and free up space.
C. Before: The components were worked on directly on the table, taking up space
D. After: Vertical storage rack for organizing, improving visibility, and freeing up workspace.

Vertical organization, visual control, and WIP optimization.

Released Space Photograph

Protected photograph after redesign.

Conclusions

- A structured five-phase Lean methodology released 304 ft² from a baseline of 868 ft² without new cleanroom construction.
- Cycle time was reduced significantly across 10 processes, confirming that workstation organization and 5S improved efficiency.
- The I-MR chart verified that the methodology was applied consistently across 25 workstations.
- Original workstation size was a significant predictor of freed space, supporting future prioritization.
- The project generated strong financial value: BCR 6.95, payback 5.02 months, and NPV $446,568.

Future Work

- Apply the methodology to other cleanroom zones.
- Develop multivariate models with additional predictors of freed space.
- Assess long-term sustainability and ergonomics.
- Integrate simulation to study airflow, contamination risk, and capacity effects.

Acknowledgements

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