Improving Efficiency in the Decommissioning of Pharmaceutical Equipment & Systems

Author: Christian J. Colón Rodríguez
Advisor: Rafael Nieves Castro, Ph.D.
Master's in Manufacturing Competitiveness

Abstract

This study presents a structured, data-driven framework to improve the efficiency, traceability, and compliance of pharmaceutical equipment decommissioning using the Lean Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology. Key inefficiencies—such as inconsistent documentation, delayed evidence review, and lack of performance metrics—were addressed through standardized checklists, peer-review checkpoints, and formalized protocols. Post-implementation analysis of 64 decommissioning reports yielded a 68.95% process yield and a sigma level of 2.0, establishing an initial benchmark for ongoing improvement. Although baseline data were unavailable, three performance metrics (efficiency, traceability, and documentation accuracy) were defined to guide future evaluation. This framework offers a replicable model for compliance-driven process improvement.

Introduction

This research applies the Lean Six Sigma DMAIC methodology to improve the efficiency, traceability, and regulatory compliance of pharmaceutical equipment decommissioning processes. The resulting framework introduces standardized tools, performance metrics, and cross-functional checkpoints to reduce variability, enhance traceability, and support consistent, audit-ready execution throughout the decommissioning lifecycle.

Background

Pharmaceutical equipment decommissioning is a critical process governed by regulatory standards such as the FDA's 21 CFR Parts 210–211 and the World Health Organization's Good Manufacturing Practices (GMP), which emphasize proper documentation, equipment cleaning, and validation. The International Society for Pharmaceutical Engineering (ISPE) provides best practice guidelines that highlight risk-based planning, cross-functional collaboration, and the use of standardized documentation to ensure regulatory compliance and operational continuity. The DMAIC framework is widely adopted in regulated environments to reduce process variation and improve efficiency. Additionally, ISO 9000 quality management standards reinforce consistent documentation, continual improvement, and audit readiness, which are essential to effective decommissioning strategies. Building on these regulatory and quality frameworks, this study proposes a structured and replicable methodology to optimize lifecycle closure activities in pharmaceutical operations.

Problem

The decommissioning of pharmaceutical equipment is a compliance-critical process frequently affected by inconsistent documentation, delayed evidence review, and limited process monitoring. These inefficiencies increase regulatory risk, drive up operational costs, and delay project timelines. The lack of standardized procedures and defined performance metrics further impairs traceability and hinders the replication of best practices across facilities. To address these challenges, this research developed a structured, GMP-aligned methodology designed to improve process efficiency, documentation accuracy, and cross-functional coordination. Core objectives included designing a traceability tool, mapping key process steps to identify variability, defining performance benchmarks, and enhancing standard operating procedures through targeted, data-driven interventions.

Methodology

This study used the Lean Six Sigma DMAIC framework to optimize pharmaceutical equipment decommissioning. In the Define phase, the project scope was established through a charter, SIPOC analysis, and stakeholder interviews. The Measure phase involved developing a data collection plan, defining key variables, and using a Value Stream Map, descriptive statistics, and I-MR charts to assess cycle time, variability, and documentation errors, establishing post-implementation benchmarks. During Analyze, root causes were identified using Fishbone diagrams, the 5 Whys, and FMEA to prioritize critical deficiencies. The Improve phase introduced standardized checklists, peer-review checkpoints, and revised procedures to address key inefficiencies. Finally, the Control phase implemented monitoring plans, statistical tools, and a RACI matrix to sustain improvements and ensure GMP and EHS compliance.

Figure 1
Value Stream Map

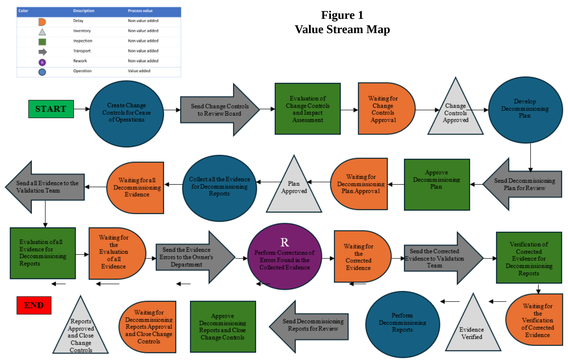


Figure 2
Capability Analysis

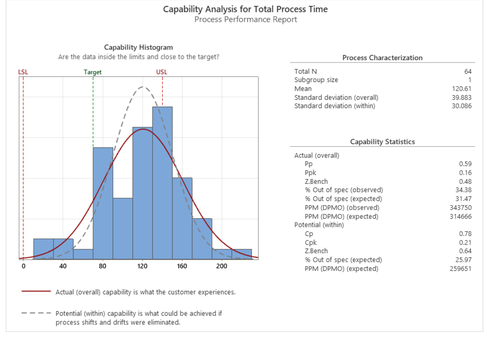


Figure 3
Boxplots

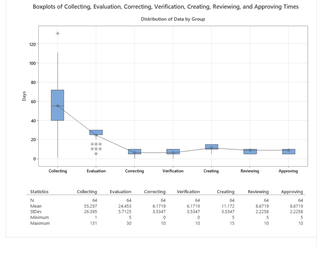
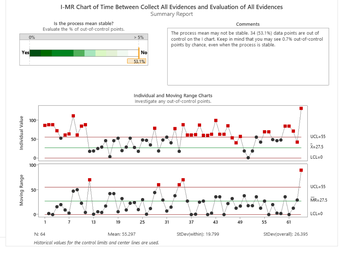


Figure 4
I-MR Chart



Results and Discussion

The application of the DMAIC framework significantly improved the pharmaceutical equipment decommissioning process by reducing inefficiencies and enhancing documentation practices. Analysis of 64 completed decommissioning reports revealed an average process duration of 120.6 days, with the greatest variability occurring during the evidence collection phase, as illustrated in the Value Stream Map (Figure 1). Capability analysis (Figure 2) yielded a sigma level of 2.0 and a process yield of 68.95%, establishing a baseline performance benchmark for ongoing monitoring. Boxplots (Figure 3) further confirmed that early stages—particularly evidence collection—exhibited the highest variability. The I-MR chart (Figure 4) demonstrated statistical instability between evidence collection and evaluation, with over 53% of data points falling outside control limits. Root cause analysis using a Fishbone Diagram and Failure Modes and Effects Analysis (Table 1) identified inconsistent documentation, lack of formal training, and the absence of performance metrics as primary contributors to inefficiency.

To address these issues, targeted solutions such as standardized checklists, peer-review checkpoints, and revised procedures were developed and prioritized based on impact and feasibility (Table 2). A cost-benefit estimate (Table 3) projected a net annual savings of $25,025, confirming the operational and financial value of the interventions. Pilot testing demonstrated early reductions in documentation errors and improved workflow consistency. These gains were consolidated in an updated decommissioning process design that streamlined tasks, clarified roles, and integrated control points for performance monitoring (Table 4). Additionally, three performance metrics—focusing on efficiency, traceability, and documentation accuracy—were defined to guide continuous improvement and compliance tracking (Table 5).

Collectively, the results confirm that structured standardization and cross-functional collaboration can significantly enhance decommissioning performance, strengthen regulatory alignment, and provide a scalable framework for future implementation.

Table 1
Failure Modes & Effects Analysis (FMEA

Process Step	Potential Failure Mode	Potential Effect of Failure	Severity	Occurrence	Detection	RPN
- Correct Documentation Errors	Corrections not applied properly	Regulatory non-compliance	9	5	6	**270**
- Collect Evidences	Incomplete documentation collected	Delays in validation	8	6	5	**240**
- Evaluate Evidences	Errors not identified	Inaccurate findings	7	5	6	**210**
- Verify Corrected Evidences	Verification misses errors	Errors passed forward	8	4	6	**192**
- Create Reports	Incorrect data in reports	Misleading final documentation	9	4	5	**180**
- Review Reports	Delays in review	Project timeline impact	6	6	4	**144**
- Approve Reports	Approval without final validation	Audit findings or rework	8	3	3	**72**
- Close Change Controls	Closure without full compliance	Non-compliance closure	9	3	2	**54**

Table 2
Proposed Solutions

Proposed Solution	Targeted Root Cause	Impact	Feasibility	Cost	Priority Score
- Create a checklist and tracking system for evidence collection	Incomplete collection of required evidences	9	8	3	**24.00**
- Introduce peer-review checkpoints for corrected documents	Corrections not properly reviewed before resubmission	9	8	4	**18.00**
- Establish revised SOPs and templates	Lack of updated documentation standards	9	7	5	**12.60**
- Integrate process metrics into SOPs and monitor regularly	No defined metrics in SOPs to monitor process performance	9	7	5	**12.60**
- Develop and implement a formal documentation training program	Missing training on revised procedures	9	6	5	**10.80**

Table 3
Cost-Benefit Estimate

Period: Yearly	FY2025	FY2026 (3% Inflation Rate)	FY2027 (3% Inflation Rate)	Totals
Cost Avoidance: 64 reports per year				
Baseline Process Cost (Estimated Hourly Rate: $55.00 / Estimated Average Time: 9,050 hours)	$ 497,750.00	$ 512,682.50	$ 528,062.98	$ 1,538,495.48
Process Cost After Improvement (10% Time Reduction)	$ 447,975.00	$ 461,414.25	$ 475,256.68	$ 1,384,645.93
Gross Cost Avoidance	**$ 49,775.00**	**$ 51,268.25**	**$ 52,806.30**	**$ 153,849.55**
Implementation Cost (Estimated Hours: 450)	$ 24,750.00	$ -	$ -	$ 24,750.00
Net Cost Avoidance	**$ 25,025.00**	**$ 51,268.25**	**$ 52,806.30**	**$ 129,099.55**
Assumptions				
• Multiple parties will interact with the process (i.e., based on availability). For the calculation of financial benefits, we are using a baseline of 64 reports per year, an estimated hourly rate of $55.00, and an average processing time of 141.4 hours per report.				
• A 10% reduction in processing time was applied to estimate cost avoidance following DMAIC-based Lean Six Sigma improvements.				
• A one-time implementation cost of $24,750 (450 hours) was included for FY2025, and a 3% annual inflation rate was applied in FY2026 and FY2027.				

Table 4
Summary of Recommended Changes in the Updated Decommissioning Process Design (To-Be)

Action	Change Description	Mapped Type	Suggested Process	Rationale
Add	"Use Checklist for Evidence Collection"	**Operation**	🔵 Blue	Adds value by standardizing and ensuring complete input at the start.
Add	"Peer-Review of Documents"	**Inspection**	🟩 Green	Quality control activity to catch errors early.
Streamline	Remove/reduce redundant "Waiting for…" steps	**Delay (eliminated)**	🟠 Orange (was) → ❌	These were non-value-adding delays now removed or reduced.
Automate	Replace "Send to…" steps with system workflow logic	**Transport (eliminated)**	▶ Gray (was) → ❌	Manual handoffs are now automated—thus reducing waste.
Enhance	Integrate performance tracking and SOP alignment	**Inspection / Operation**	🔵 Blue or 🟩 Green	Enables continuous monitoring and performance tracking.

Table 5
Performance Metrics

Performance Metric	Definition	Initial Benchmark Value	Data Source
- Decommissioning Efficiency	Average number of days from evidence collection to final report approval.	*e.g., 120.6 days*	Time study of 64 decommissioning reports
- Traceability	Percentage of equipment with complete documentation from initiation to closure.	*e.g.,* 98%	Checklist tracking & lifecycle log review
- Documentation Accuracy	Percentage of records requiring correction due to missing or inaccurate data.	*e.g., 31% error rate*	Peer-review checkpoints & error analysis

Conclusions

This research demonstrated that applying the Lean Six Sigma DMAIC framework can significantly enhance the efficiency, traceability, and regulatory compliance of pharmaceutical equipment decommissioning. Despite the absence of baseline data, the project established a sigma level of 2.0 and defined key performance metrics to guide continuous improvement. Targeted interventions—such as standardized documentation checklists and peer-review checkpoints—reduced errors, improved consistency, and supported post-implementation monitoring. A cost-benefit analysis projected a net annual savings of $25,025, reinforcing the operational and financial impact of the improvements. By fostering cross-functional collaboration and aligning with GMP and EHS standards, the study offers a scalable, compliance-ready model that contributes to best practices in pharmaceutical quality systems.

Future Work

Future efforts will focus on validating the framework across diverse facilities and conducting multi-site studies with economic and longitudinal assessments. Additional exploration of automated monitoring, predictive analytics, and AI-based maintenance may further enhance proactive decommissioning strategies. These efforts aim to strengthen long-term sustainability and support broader adoption across the pharmaceutical industry.

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