Improving Efficiency in the Decommissioning of Pharmaceutical Equipment & Systems

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Abstract *— This study presents a structured, data-driven framework to improve the efficiency, traceability, and compliance of pharmaceutical equipment decommissioning processes. Using the Lean Six Sigma DMAIC methodology, the project addressed key inefficiencies (such as inconsistent documentation, delayed evidence review, and gaps in process monitoring) through targeted interventions such as standardized checklists, peer-review checkpoints, and formalized documentation protocols. Post-implementation analysis of 64 decommissioning reports yielded a sigma level of 2.0 and a 68.95% process yield, establishing an initial benchmark for ongoing monitoring. Although baseline data were unavailable, three core performance metrics (decommissioning efficiency, traceability, and documentation accuracy) were defined to support future evaluation and continuous improvement. Aligned with Good Manufacturing Practices (GMP) and Environmental Health and Safety (EHS) standards, the framework offers a replicable model for optimizing compliance-driven decommissioning activities. These findings contribute to best practices in pharmaceutical operations by improving process consistency, reducing delays, and supporting scalable standardization.*

Keywords *— Asset Lifecycle, Decommissioning Processes, Lean Six Sigma, Pharmaceutical Equipment.*

PROBLEM STATEMENT

The decommissioning of pharmaceutical equipment is a complex, compliance-sensitive process that must align with Good Manufacturing Practices (GMP), Environmental Health and Safety (EHS) regulations, and international quality standards. Despite its critical role in supporting regulatory readiness and operational continuity, decommissioning processes are often hindered by inconsistent documentation, prolonged evidence review cycles, lack of standardized workflows, and limited process monitoring. These inefficiencies introduce regulatory risks, elevate operational costs, and delay project completion. Moreover, the absence of defined performance metrics and cross-functional coordination impedes the ability to track progress, ensure accountability, and replicate best practices across facilities.

As pharmaceutical organizations face growing regulatory scrutiny and operational complexity, there is an urgent need for a standardized methodology that enhances efficiency, ensures traceability, and sustains compliance throughout the equipment lifecycle. This study addresses that need by applying a Lean Six Sigma framework to optimize pharmaceutical equipment decommissioning practices.

RESEARCH DESCRIPTION

This research develops a structured, data-driven methodology to improve the efficiency, traceability, and regulatory compliance of pharmaceutical equipment and system decommissioning. Applying the Lean Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) framework, the study systematically identifies and addresses critical inefficiencies across the decommissioning lifecycle.

Key process areas examined include GMP-compliant documentation practices, EHS-aligned cleaning and disposal, exit calibration, data archiving, and asset lifecycle closure. Targeted interventions (such as standardized documentation checklists, peer-review checkpoints, and evidence tracking tools) were introduced to reduce process variability and strengthen compliance. Emphasis was placed on cross-functional collaboration among Quality Assurance (QA), Engineering, Information Technology (IT), Environmental Health and Safety (EHS), and Manufacturing and Operations teams. The resulting methodology offers a scalable and replicable approach designed to enhance decommissioning outcomes while maintaining operational continuity and meeting global regulatory expectations.

RESEARCH OBJECTIVES

The primary objective of this study is to develop a standardized and GMP-compliant approach for measuring and documenting the decommissioning of pharmaceutical equipment and systems. By establishing performance metrics and collecting benchmark data, the study seeks to identify inefficiencies, enhance process consistency, and support regulatory compliance throughout the decommissioning lifecycle. To achieve this objective, the study pursued the following specific objectives:

- Design a prototype asset tracking tool capable of logging equipment IDs, decommissioning status, and documentation milestones, ensuring traceability for 100% of assets in the current dataset.
- Develop a Value Stream Map capturing at least 7 of the 13 key steps in the decommissioning process, using time study data to identify cycle time variability and areas for standardization.
- Conduct a descriptive analysis of documentation quality using a sample of at least 50 decommissioning records, categorizing documentation errors to establish an initial benchmark error rate.
- Define and document three performance metrics (traceability, documentation accuracy and decommissioning efficiency) to serve as benchmarks for future monitoring and continuous improvement.

RESEARCH CONTRIBUTIONS

This research delivers a practical contribution to pharmaceutical operations by establishing a scalable and replicable framework for improving equipment and system decommissioning. Grounded in the Lean Six Sigma DMAIC methodology, the study provides a structured approach that enhances process consistency, strengthens documentation practices, and improves traceability across the asset lifecycle. The implementation of standardized tools, along with the introduction of performance monitoring strategies, helped address longstanding inefficiencies in documentation management and workflow coordination. The achievement of a post-implementation sigma level of 2.0 established a quantifiable baseline for ongoing process evaluation.

Furthermore, by formalizing cross-functional roles and promoting greater alignment between quality, engineering, and operational teams, the project supports more sustainable and audit-ready decommissioning practices. This work contributes to the broader field by offering a model that pharmaceutical organizations can adapt to meet increasing regulatory expectations and operational demands.

LITERATURE REVIEW

The decommissioning of pharmaceutical equipment is a critical, though often under documented, component of the pharmaceutical manufacturing lifecycle. It ensures the safe, compliant, and efficient retirement of assets in alignment with GMP and EHS standards. Although there is limited peer-reviewed research specifically dedicated to decommissioning, existing regulatory frameworks, industry guides, and quality improvement methodologies offer relevant insights to inform this study.

Foundational regulatory direction is provided by the U.S. Food and Drug Administration (FDA) through 21 CFR Parts 210 and 211, which mandate the proper control, maintenance, and cleaning of drug manufacturing equipment [1]. These regulations emphasize that any process impacting product quality, including equipment retirement, must be documented and validated. The World Health Organization (WHO) reinforces these principles through its GMP guidelines, underscoring the importance of quality assurance throughout the equipment lifecycle [2].

The International Society for Pharmaceutical Engineering (ISPE) addresses decommissioning more directly in its Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities. This resource provides structured recommendations for planning, executing, and documenting decommissioning activities. It highlights the importance of risk-based decision-making, cross-functional collaboration, and the use of standardized documentation tools to ensure regulatory compliance and operational continuity during site closures or system retirements [3].

From a process improvement standpoint, the Lean Six Sigma methodology offers a practical approach for identifying inefficiencies and improving decommissioning workflows. The DMAIC framework is particularly useful in highly regulated environments where process variation must be minimized, and documentation must be precise. Lean Six Sigma tools such as root cause analysis, Failure Mode and Effects Analysis (FMEA), and capability analysis allow for targeted improvements in efficiency, accuracy, and compliance [4].

In addition, ISO 9000 standards provide a broader quality management framework that complement regulatory guidance. These standards emphasize documentation integrity, risk-based thinking, and continual improvement, principles that align closely with the goals of effective decommissioning processes [5]. ISO 9000 does not prescribe specific decommissioning steps but provides a structure that ensures consistency and audit readiness.

Collectively, these sources establish a strong foundation for the need for a standardized, data-driven approach to pharmaceutical equipment decommissioning. Building on these principles, this study develops and validates a replicable framework that addresses documentation gaps, improves asset tracking, and strengthens monitoring practices, contributing to the formalization of end-of-lifecycle management strategies in pharmaceutical environments.

METHODOLOGY

This study applied the Lean Six Sigma DMAIC methodology to improve the efficiency, traceability, and compliance of the pharmaceutical equipment decommissioning process. DMAIC is a structured, data-driven framework commonly used in regulated industries to reduce variability, eliminate non-value-adding activities, and improve process performance. It was selected for its ability to integrate operational, quality, and compliance requirements into a systematic improvement effort.

The *Define Phase* established the project's scope, objectives, and deliverables through the development of a project charter and a SIPOC diagram outlining the decommissioning process. Stakeholder interviews with representatives from QA, Engineering, IT, EHS, and Operations were conducted to validate process gaps and confirm areas of concern.

The *Measure Phase* involved collecting post-implementation data to assess decommissioning process performance. A Value Stream Map was created to visualize the workflow and identify bottlenecks and delays. A data collection plan and operational definitions for key variables were established. Analysis of 64 decommissioning records using descriptive statistics, histograms, boxplots, and individual-moving range (I-MR) charts evaluated process variability, and a sigma level calculation was performed to establish a performance benchmark.

The *Analyze Phase* focused on identifying root causes of inefficiencies and documentation variability. A Fishbone diagram and the 5 Whys technique were used to explore contributing factors, while a FMEA assessed the severity, occurrence, and detectability of failure modes. Risk Priority Numbers (RPNs) were calculated to prioritize areas for improvement.

During the *Improve Phase*, solutions were developed and prioritized based on impact, feasibility, and cost. Interventions included standardized checklists, peer-review checkpoints, revised standard operating procedures (SOPs) with performance metrics, and a tracking tool for evidence collection. Quick wins were implemented first, and pilot testing validated the effectiveness of improvements in reducing errors and cycle times.

The *Control Phase* focused on sustaining improvements and ensuring long-term compliance with GMP and EHS standards. A control plan was developed with updated procedures, proposed training protocols, and Statistical Process Control (SPC) tools to monitor key metrics. A RACI (Responsible, Accountable, Consulted, Informed) chart clarified stakeholder responsibilities, and periodic internal audits were recommended to reinforce accountability and promote continuous improvement.

The *Research Timeline* was completed over an eight-week period, following the structured sequence of the Lean Six Sigma DMAIC methodology.

- Week 1*:* Project charter development, stakeholder interviews, and SIPOC analysis.
- Weeks 2–3: Data collection, Value Stream Map development, and performance benchmarking.
- Week 4: Root cause analysis using Fishbone diagram, 5 Whys technique, and FMEA assessments.
- Weeks 5–6: Solution design, prioritization, and pilot implementation of selected improvements.
- Week 7: Development of the control plan and proposed training protocols.
- Week 8: Compilation of final report, conclusions, and recommendations.

This structured approach ensured that all improvements were not only data-driven and compliant with regulatory expectations, but also sustainable, scalable, and aligned with operational goals.

RESULTS AND DISCUSSION

The implementation of the Lean Six Sigma DMAIC methodology significantly improved the pharmaceutical equipment decommissioning process by reducing inefficiencies, enhancing documentation practices, and aligning with regulatory requirements. This section presents key outcomes from each DMAIC phase, along with a discussion of their impact on process performance, compliance, and operational sustainability.

Define Phase

A detailed SIPOC analysis and stakeholder interviews revealed that the most critical inefficiencies occurred during the documentation and approval stages of the decommissioning process. Stakeholders, particularly from QA, Engineering, IT, EHS, and Operations, identified unclear roles, inconsistent practices, and lack of monitoring as recurring pain points. These insights informed the project's scope, objectives, and improvement strategy.

Measure Phase

The Measure Phase focused on collecting post-implementation data to assess decommissioning process performance. Due to the absence of pre-intervention baseline data, post-implementation metrics were used to establish a performance benchmark. A Value Stream Map was developed to visualize the decommissioning workflow, identify key process steps, and highlight bottlenecks and delays (Figure 1). The map illustrated that significant delays occurred during evidence collection, evaluation, and documentation correction activities, confirming early observations of process inefficiency. A data collection plan was also established to define operational variables, including process cycle time, documentation errors, and rework frequency.

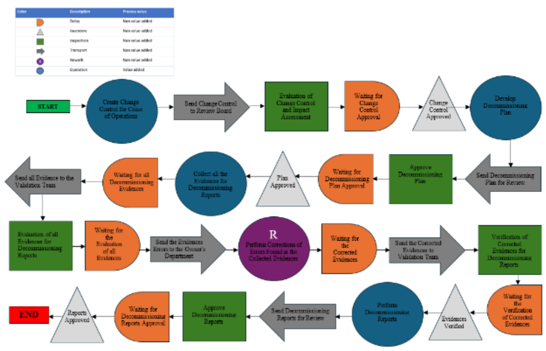


Figure 1
Value Stream Map

A sample of 64 completed decommissioning records was analyzed using descriptive statistics, histograms, boxplots, and I-MR charts to evaluate process variability. The average total process duration from initiation to final approval was 120.6 days, with a standard deviation of 39.9 days, indicating substantial variability. Delays were most pronounced during early stages, particularly in evidence collection, evaluation, and documentation correction.

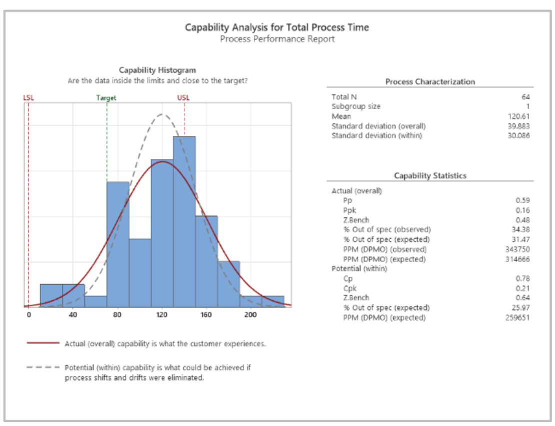
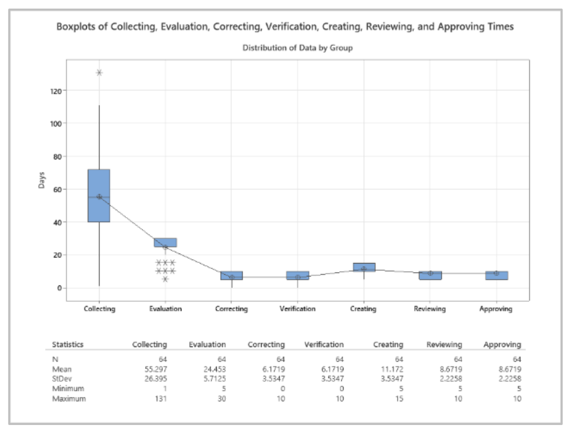


Figure 2
Capability Analysis

A process capability analysis was conducted to evaluate overall process performance and determine its ability to meet specification limits (Figure 2). The analysis yielded a sigma level of 2.0, based on a total of 159 observed defects across 512 defect opportunities, resulting in a process yield of 68.95%. The observed process performance index (Ppk) was 0.16, the standardized Z value (Z.Bench) was 0.48, and the defect rate was approximately 343,750 defects per million opportunities (DPMO). Even under ideal within-subgroup conditions, the process capability index (Cp) was 0.78 and the process capability index adjusted for mean shift (Cpk) was 0.21, confirming that the process was not capable of consistently meeting expectations. These findings established a Sigma Benchmark for future performance monitoring and improvement cycles.

To further explore process variability across specific stages, boxplots were generated for each key step in the decommissioning workflow (Figure 3). The evidence collection phase exhibited the greatest variation, with a mean duration of 55.3 days and a maximum of 131 days. In contrast, later steps such as correcting, verification, and approving were more stable, each averaging under 9 days. The presence of outliers in the evaluation phase further emphasized the need for greater process standardization.



Statistics	Collecting	Evaluation	Correcting	Verification	Creating	Reviewing	Approving
N	64	64	64	64	64	64	64
Mean	55.297	24.453	6.1719	6.1719	11.172	8.6719	8.6719
StDev	26.395	5.7125	3.5347	3.5347	3.5347	2.2258	2.2258
Minimum	1	5	0	0	5	5	5
Maximum	131	30	10	10	15	10	10

Figure 3
Boxplots

These results indicated that early-stage documentation activities were the most significant contributors to overall process inefficiency.

To assess statistical control between critical steps, an I-MR chart was constructed for the time between evidence collection and evaluation (Figure 4). The analysis showed that 34 of 64 data points (53.1%) were outside control limits, confirming instability well beyond the 0.7% expected for a stable process. The chart displayed a center line of 27.5 days, with control limits ranging from 0 to 55 days.

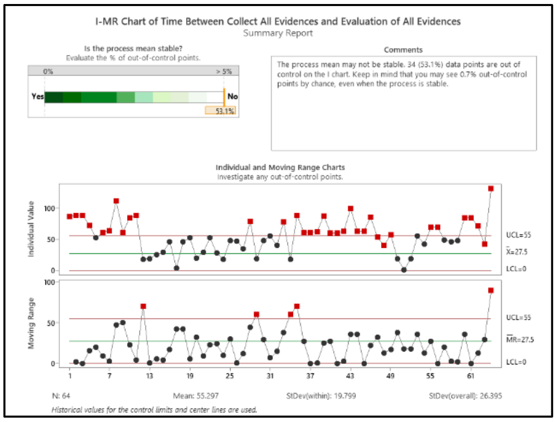


Figure 4
I-MR Chart

Collectively, the Value Stream Map, capability analysis, boxplots, and I-MR chart confirmed that early-stage documentation activities were primary sources of variability and that the process between evidence collection and evaluation was statistically unstable, requiring targeted standardization efforts to improve predictability and performance.

Analyze Phase

The Analyze Phase focused on identifying the root causes of process inefficiencies and documentation variability. Root cause analysis tools, including a Fishbone (Ishikawa) diagram and the 5 Whys technique, were used to explore contributing factors across people, methods, materials, and measurement categories. Key findings included the lack of formal documentation training, inconsistent procedures across departments, and missing defined performance metrics within existing SOPs.

A Failure Mode and Effects Analysis (FMEA) was performed to quantify risk at each process step. Risk Priority Numbers (RPNs), calculated by combining severity, occurrence, and detection scores, were used to prioritize areas for improvement. As shown in Table 1, the FMEA identified "Correct Documentation Errors" (RPN = 270) and "Collect Evidences" (RPN = 240) as the most critical failure modes. These insights confirmed the need to prioritize improvements in documentation accuracy, evidence collection, and quality control mechanisms to enhance the overall effectiveness and reliability of the decommissioning process.

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**

Improve Phase

Targeted solutions were developed and prioritized based on their expected impact, feasibility, and cost, addressing the key deficiencies identified during the Analyze Phase. These interventions included the creation of a standardized documentation checklist and evidence tracking system, the introduction of peer-review checkpoints for corrected documents, the update and standardization of SOPs and documentation templates, the integration of process metrics into SOPs, and a formal training program to reinforce the use of revised documentation procedures, serving as a supportive measure alongside primary interventions.

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 2 summarizes the proposed solutions, their targeted root causes, and prioritization scores. The checklist and peer-review checkpoint were implemented first as quick wins due to their low complexity and immediate operational benefits.

A cost-benefit estimate was conducted to assess the financial impact of implementing the prioritized improvements identified in the decommissioning process. Table 3 summarizes the estimated baseline costs, anticipated savings, and net cost avoidance following implementation.

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.

Using an estimated 64 reports processed annually, baseline costs were calculated based on current labor time and rates. With a conservative 10% reduction in process time, driven by interventions such as checklists, peer-review checkpoints, and standardized SOPs, the analysis projected a gross cost avoidance of $49,775. After accounting for an implementation cost of $24,750, the estimated net savings reached $25,025 within the first year. These results demonstrate that the proposed improvements are both operationally effective and financially sound, yielding measurable efficiency gains and a clear return on investment with modest resource use.

Initial pilot testing with a small sample validated the practical feasibility of these improvements, demonstrating early reductions in documentation errors and process cycle times. The updated "To-Be" process map reflected a streamlined workflow with improved consistency and traceability. Table 4 summarizes the specific changes recommended in the updated decommissioning process design, including proposed actions, mapped process types, and their rationale.

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.

The initial pilot, though limited in scope, showed promising results; further testing with a broader sample is recommended to confirm long-term effectiveness and scalability.

As part of the Improve Phase, it was essential not only to implement targeted solutions but also to define how their impact would be measured over time. To support ongoing performance monitoring and ensure alignment with project objectives, three key performance metrics were developed using data collected during the post-implementation period. These metrics focus on the core areas of efficiency, traceability, and documentation accuracy, and serve as the initial benchmarks for evaluating future improvements in the decommissioning process. Table 5 summarizes each performance metric, its operational definition, and the corresponding baseline values based on the current dataset.

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

Control Phase

The Control Phase focused on sustaining improvements and ensuring long-term compliance with GMP and EHS standards. A formal control plan was developed, including updated procedures, proposed training protocols, and the recommendation of SPC tools to monitor key performance metrics.

A RACI matrix was created to clarify stakeholder responsibilities across QA, Engineering, IT, EHS, and Operations teams (Table 6). This structure was designed to reinforce task ownership and facilitate coordinated cross-functional execution.

Table 6
RACI Matrix

Implementation Task	QA	Engineering	IT	EHS	Operations
- Develop documentation checklist	A	C	I	I	R
- Standardize documentation procedures	A	C	I	I	R
- Implement peer-review step	R	C	I	I	C
- Update SOPs with performance metrics	A	R	C	I	C
- Deploy tracking system for evidence collection	A	R	C	I	C
- Coordinate equipment cleaning & validation	A	R	I	C	C
- Manage system decommissioning & data archiving	A	C	R	I	I
- Ensure hazardous material compliance	A	I	I	R	C
- Minimize operational disruptions during implementation	A	C	C	I	R

To support ongoing monitoring and compliance assurance, a control plan was developed specifying key metrics, target values, monitoring frequencies, responsible parties, and escalation triggers (Table 7).

Table 7
Control Plan Metrics, Monitoring Methods, & Escalation Triggers

Metric	Target Value	Monitoring Frequency	Responsible Party	Control Method	Escalation Trigger
Time Between Evidence Collection and Evaluation	≤ 55 days	Weekly	QA	SPC Chart	> 55 days (2+ reports)
Time Between Error Correction and Verification	≤ 10 days	Weekly	QA	SPC Chart	> 10 days (2+ reports)
Documentation Completeness Rate	100%	Monthly	QA	Document Audit	< 95%
Number of Rework Incidents per Report	≤ 1	Monthly	Operations	Trend Analysis	> 1 incident
Checklist Compliance Rate	≥ 95%	Weekly	Operations	Checklist Audit	< 90%

The control plan incorporates SPC charts for monitoring cycle time metrics, document audits for ensuring documentation completeness, and checklist audits for compliance verification. These monitoring tools were selected to enable early detection of process deviations and to trigger escalation protocols when predefined thresholds are exceeded. Additionally, periodic internal audits were recommended to reinforce accountability and promote continuous improvement.

Discussion

The structured application of the Lean Six Sigma DMAIC methodology established a quantifiable post-implementation benchmark for evaluating the pharmaceutical equipment decommissioning process. Although baseline data were unavailable, analysis yielded a sigma level of 2.0 and identified significant variability in documentation quality and evidence review timelines, critical factors in GMP-regulated environments where traceability and compliance are essential.

Root cause analysis revealed that the most significant contributors to inefficiency were the incomplete collection of evidence, insufficient review of corrected documents, and the lack of defined performance metrics in existing SOPs. These findings were validated through capability analysis, I-MR charts, and boxplots, which consistently highlighted early-stage documentation activities as primary sources of process variation. The FMEA further prioritized these risks, guiding the selection of targeted solutions.

Initial pilot testing confirmed the feasibility of prioritized interventions, which included the introduction of checklists, peer-review checkpoints, and SOP updates. A cost-benefit estimate projected a net annual savings of $25,025, reinforcing the operational and financial value of these improvements. Several control measures, such as monitoring tools and department-specific training, were developed to reinforce sustainability and compliance. This initiative provides a replicable and scalable model for regulatory-aligned decommissioning practices.

Future improvements should emphasize continuous performance tracking, iterative refinement of documentation workflows, and broader adoption of automation and digital evidence tracking. These efforts will further enhance process reliability, compliance readiness, and operational efficiency across pharmaceutical manufacturing environments.

Conclusion

This study presented a structured, evidence-based framework to improve the pharmaceutical equipment decommissioning process using the Lean Six Sigma DMAIC methodology within a regulated manufacturing environment. The project addressed critical inefficiencies—such as documentation variability, the absence of standardized procedures, and verification delays—through the design and implementation of targeted interventions grounded in quality systems and operational excellence principles.

Due to the unavailability of pre-intervention baseline data, the performance metrics established serve as an initial post-implementation benchmark. Analysis of 64 decommissioning reports across eight key process opportunities resulted in a sigma level of 2.0 and a process yield of 68.95%. These metrics provide a valuable reference point for ongoing monitoring and continuous improvement. Improvements such as standardized checklists, peer-review checkpoints, and enhanced documentation workflows contributed to greater consistency, reduced rework, and stronger alignment with GMP requirements.

A preliminary cost-benefit estimate projected a net annual savings of $25,025, demonstrating that the interventions were not only operationally impactful but also financially justified. Pilot testing validated the feasibility of the proposed solutions, further supporting their scalability and adaptability.

The study contributes to the advancement of systematic approaches for pharmaceutical equipment decommissioning by integrating quality assurance, engineering, regulatory compliance, and operational efficiency. While meaningful improvements were achieved, limitations include the absence of baseline data and the reliance on a single implementation site. Future research should address these gaps by incorporating pre- and post-intervention data, validating the framework across diverse facility types, and conducting multi-site studies with economic and longitudinal assessments to evaluate the sustainability and scalability of the improvements.

Based on these findings, organizations seeking to enhance pharmaceutical equipment decommissioning processes are encouraged to:

- Adopt standardized documentation checklists to improve evidence completeness and reduce delays.
- Implement peer-review checkpoints to minimize rework and strengthen regulatory compliance.
- Establish early cross-functional collaboration among QA, Engineering, IT, EHS, and Operations.
- Use post-implementation metrics as benchmarks for continuous improvement.
- Leverage digital tools to increase traceability and reduce manual errors.
- Apply SPC monitoring systems to reinforce process stability.
- Scale the implementation model across multiple facilities with contextual adaptations.

Future work may also explore automated monitoring, predictive analytics for risk identification, and emerging technologies such as AI-based predictive maintenance. These innovations could enhance forecasting capabilities, support proactive planning, and further elevate operational excellence across pharmaceutical manufacturing environments.

References

[1] U.S. Food and Drug Administration. Code of Federal Regulations Title 21 – Parts 210 and 211: Current Good Manufacturing Practice for Finished Pharmaceuticals. U.S. Department of Health & Human Services.

[2] World Health Organization. Good Manufacturing Practices for Pharmaceutical Products: Main Principles. WHO Technical Report Series, No. 986, Annex 2, 2014.

[3] International Society for Pharmaceutical Engineering (ISPE). ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities. ISPE, June 2017.

[4] Munro, R. A., Ramu, G., & Zrymiak, D. J. (2022). The American Society for Quality's (ASQ) Certified Six Sigma Green Belt Handbook (3rd ed.). Milwaukee, WI: ASQ Quality Press

[5] International Organization for Standardization (ISO). ISO 9000: Quality Management Systems – Fundamentals and Vocabulary. ISO, 2015.