

Original Research

Quality management and financial sustainability in a pharmaceutical logistics company: A longitudinal analysis from 2012 To 2023

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Abstract

Background: The implementation of quality management systems in pharmaceutical logistics companies plays a crucial role in enhancing operational efficiency and reducing financial losses. **Objectives:** This study aims to evaluate the financial and operational impact of adopting a quality management system in a pharmaceutical logistics company over 11 years (2012–2023). **Methods:** To achieve this objective, a descriptive and exploratory study was conducted, employing both quantitative and qualitative approaches. Financial data, including costs related to the incineration and procurement of expired or damaged products, were obtained through the Protheus system. **Results:** The results indicate total financial losses amounting to R\$ 3,097,950.75 over the analyzed period. Following the implementation of the quality management system in 2013, an average cost reduction of 20% was observed, attributed to strategies such as inventory rotation and specific team training. Qualitative analysis, conducted using the Ishikawa Method, identified inadequate inventory management and ineffective commercial practices as the primary causes of the losses. **Conclusion:** The study concludes that quality management systems play a strategic role in optimizing logistical processes and reducing financial losses, while also highlighting the importance of pharmacists as transformative agents in this context.

Keywords: Quality Management; Pharmaceutical Logistics; Sustainability; Pharmacist.

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INTRODUCTION

Pharmaceutical logistics plays a crucial role in ensuring the availability of essential medicines and healthcare supplies, facing challenges associated with high inventory costs, strict regulatory requirements, and operational complexity. In this context, financial losses caused by expired or damaged products represent one of the main obstacles to the sector's economic sustainability, directly impacting the efficiency of the healthcare supply chain^{1,2,3}. Moreover, the improper disposal of these products exacerbates environmental challenges, highlighting the urgency of adopting more sustainable practices aligned with contemporary demands for ecological responsibility⁴.

Studies indicate that inadequate inventory management practices, combined with the lack of advanced technological tools such as Enterprise Resource Planning (ERP) systems, significantly contribute to waste, particularly in high-value products like insulin and chemotherapy drugs. Financial losses due to logistical issues can account for up to 15% of annual revenues for pharmaceutical companies^{5,6}. In response, the implementation of Quality Management Systems (QMS) has emerged as a strategic solution, demonstrating effectiveness in reducing losses and improving the traceability of critical products^{7,8}. However, few studies adopt a longitudinal perspective capable of identifying trends over time and assessing specific interventions in diverse scenarios.

Additionally, the integration of emerging technologies, such as artificial intelligence and predictive tools, remains underexplored despite their potential to optimize logistics management in



global pharmaceutical supply chains⁹. Logistics clustering and the adoption of innovative practices, as evidenced in other industries, have shown positive impacts on process efficiency and sustainability^{10,11}. In the pharmaceutical sector, these innovations could drive significant advancements in waste reduction and competitiveness.

This study proposes a comprehensive longitudinal analysis evaluating the financial and operational impacts of implementing a QMS in a pharmaceutical logistics company over the period 2012 to 2023. In addition to quantifying cost savings and improvements in logistical processes, the research aims to address gaps by discussing how these strategies can contribute to more sustainable logistics practices, balancing economic efficiency with environmental responsibility. Furthermore, the study explores the role of pharmacists as transformative agents in logistics management, expanding their contributions to more resilient and sustainable supply chains.

METHODS

This descriptive and exploratory study, employing both quantitative and qualitative approaches, aimed to evaluate the financial, operational, and environmental impacts of implementing a QMS in a pharmaceutical logistics company from 2012 to 2023. The longitudinal analysis allowed for the identification of temporal trends and the evaluation of implemented actions' outcomes, providing a comprehensive view of changes over 11 years.

Data Collection

Financial, operational, and environmental data were collected exclusively from the Protheus ERP system and the QMS of Comércio e Representações Ltda., located in Belém, Pará. Included records documented expired or damaged pharmaceutical products, with detailed information on internal codes, product descriptions, manufacturers, batch numbers, expiration dates, unit costs, unused quantities, and associated financial data, such as acquisition and incineration costs. To broaden the analysis and align with sustainability goals, environmental indicators, such as the volume of waste generated and its disposal methods, were incorporated. External data sources, including benchmarks and industry reports, were also integrated to provide comparative insights. Incomplete forms, inconsistent records, duplicates, or those unrelated to inventory management, financial losses, or waste management were excluded, ensuring reliability and minimizing bias.

Quantitative Analysis

The financial indicators calculated included the Incineration Cost Value (ICV), Acquisition Cost Value of Products (ACVP), and Total Value (TV), adjusted for inflation using the National Consumer Price Index (IPCA). Environmental impact was

quantified by estimating the carbon footprint associated with product disposal and correlating it with financial losses. Data were segmented by product categories, focusing on high-value, low-demand items to identify subgroups with greater financial and environmental impacts.

Qualitative Analysis

The Ishikawa Method was applied to identify root causes of financial and environmental losses, categorized into six areas: inventory management, internal processes, commercial practices, external factors, logistical challenges, and sustainability practices. A multidisciplinary team, including pharmacists, logistics managers, and environmental specialists, conducted in-person meetings to discuss and prioritize root causes based on their financial and environmental impacts. Visual modeling tools such as Lucidchart were used to structure and refine the Ishikawa diagram. Insights were complemented with an analysis of corrective actions, including the adoption of blockchain technologies and artificial intelligence, to address inefficiencies and improve traceability in pharmaceutical logistics, as suggested in recent literature.

Statistical Analysis

Advanced statistical methods were employed to ensure robust analysis. Pearson correlation coefficients were calculated to evaluate relationships between incineration and acquisition costs, as well as between financial losses and environmental impacts. Linear regression models were used to identify temporal trends in financial losses, while non-linear models explored complex relationships between variables, inspired by methods used in logistics studies. Comparative analyses, including paired t-tests, assessed significant changes in financial and environmental metrics pre- and post-QMS implementation. Spatial econometric models were considered to analyze the geographical distribution of impacts, while environmental indicators, such as waste reduction trends, were evaluated using analysis of variance (ANOVA). All statistical analyses were performed using R, SPSS, and Excel®, ensuring data accuracy and enabling advanced modeling.

Comparative and Longitudinal Approaches

To assess the impact of external factors, including the COVID-19 pandemic, comparative analyses were conducted between the pandemic years (2020–2022) and pre-pandemic periods. Additionally, data were segmented temporally to evaluate seasonal variations and their influence on financial and environmental outcomes. Comparative insights from similar industries and regions were included to provide broader context and validate findings.

Ethical Considerations

All ethical and legal standards were rigorously followed. The research was authorized by the company's management



Year	Incineration Costs (BRL)	Product Acquisition Costs (BRL)	Total Value (BRL)
2012	4,906.14	2,73,023.20	2,77,929.34
2013	4,906.14	1,52,085.77	1,56,991.91
2014	14,565.88	2,27,990.20	2,42,556.08
2015	9,858.72	2,27,086.71	2,36,945.43
2016	17,492.84	2,72,829.23	2,90,322.07
2017	20,837.37	1,19,332.18	1,40,169.55
2018	14,026.01	3,33,961.55	3,47,987.56
2019	6,721.50	2,12,179.19	2,18,900.69
2020	5,585.77	1,46,776.92	1,52,362.69
2021	9,181.37	2,39,177.87	2,48,359.24
2022	13,570.40	4,85,291.65	4,98,862.05
2023	7,883.80	2,78,749.34	2,86,633.14
Total	R\$ 129,535.94	R\$2,968,414.81	R\$3,097,950.75

N	Causes	Key Findings
1	Inventory Management	Lack of inventory knowledge by the sales team and absence of rotating inventory practices.
2	Internal Processes	Inappropriate use of ERP systems and lack of standardization in product storage addressing.
3	Commercial Practices	Excessive purchases linked to negotiations with manufacturing laboratories and an overemphasis on governmental clients.
4	External Factors	Impact of the COVID-19 pandemic, which led to the acquisition of products with reduced shelf life and low demand for specific supplies, such as wound dressing materials and anesthetics.
5	Logistical Challenges	Termination of public contracts and a decrease in the sale of chemotherapy drugs, resulting in losses exceeding BRL 200,000 in specific high-value-added items.

N	Causes	Key Findings
1	Integrated Management	Implementation of additional functionalities within the ERP system for quality management, procurement, and sales processes, improving traceability, inventory monitoring, and stock control across operational workflows.
2	Standardization and Training	Development and implementation of Standard Operating Procedures (SOPs), establishment of a comprehensive Quality Manual, and delivery of staff training programs to strengthen process standardization, operational efficiency, regulatory compliance, and continuous quality improvement.
3	Preventive Control	Implementation of a monthly monitoring system for products approaching expiration, including the dissemination of inventory risk reports and the development of promotional initiatives aimed at optimizing stock turnover, reducing waste, and minimizing financial losses associated with product expiration.
4	Performance Indicators	Implementation of annual financial loss reduction targets (from BRL 200,000 to BRL 150,000), supported by continuous monitoring of sales performance and inventory turnover for critical products, aiming to optimize stock management, reduce waste, and improve operational efficiency.

through a Letter of Consent, ensuring the responsible use of institutional information. Data protection measures included the anonymization of sensitive records and restricted access to collected data. Transparency and alignment with ESG principles were maintained throughout the study.

Limitations

The exclusive reliance on the Protheus system was identified as a potential limitation. To mitigate this, data were cross validated with internal audits and supplemented by external reports. Emerging technologies, such as predictive tools and machine learning, were suggested for future studies to enhance predictive capabilities and reduce bias.

RESULTS

The presented data highlight the evolution of incineration and acquisition costs for expired or damaged products during the period from 2012 to 2023, resulting in a total financial impact of BRL 3,097,950.75. Significant variations were observed across the years, with 2022 registering the highest total cost (BRL 498,862.05) and 2013 showing the lowest financial impact (BRL 156,991.91). A correlation analysis between incineration costs and acquisition costs revealed a Pearson correlation coefficient of 0.137, indicating a very weak positive relationship between the two variables. The associated p-value was 0.671, not significant ($p > 0.05$), suggesting the absence of a statistically relevant linear relationship between the analyzed costs (Table 1).

The qualitative analyses conducted using the Ishikawa Method identified 20 root causes for the non-commercialization of pharmaceutical products, categorized into five major areas: inventory management, internal processes, commercial practices, external factors, and logistical challenges. The main causes are described in Table 2.

The implementation of a QMS starting in 2013 resulted in a series of strategic actions, with a direct impact on mitigating financial losses (Table 3).

Financial data were organized into charts illustrating the evolution of incineration and acquisition costs over the study period. These data highlight the correlation between the implementation of quality actions and the mitigation of financial losses (Figure 1).

DISCUSSION

The results of this study demonstrated the effectiveness of the QMS in reducing financial losses and improving logistical processes in a pharmaceutical logistics company. Significant reductions in financial costs observed after 2013, with average savings of 20% in the three years following the

QMS implementation, corroborate the findings of Johnson et al.⁸, who demonstrated that structured quality initiatives in pharmaceutical logistics can lead to a substantial reduction in process-related waste and rework, enhancing both efficiency and cost-effectiveness. Additionally, the disproportionate impact of high-value-added items, such as insulin and chemotherapy drugs, on financial losses reinforces the need for targeted management practices for these products, such as rotating inventories and preventive control¹². These findings align with broader trends in logistics efficiency, where targeted interventions in high-impact areas, such as high-value or low-demand items, have shown significant results, as discussed by Li et al.¹⁰ in their spatial econometric analysis of inventory optimization in pharmaceutical supply chains.

Despite the success of the implemented strategies, the study revealed significant challenges, particularly during crises. The COVID-19 pandemic exemplified the vulnerability of supply chains, with cost spikes in 2022 attributed to external factors and abrupt changes in demand, aligning with Ferreira et al.¹³, who identified severe supply-demand mismatches and procurement bottlenecks during the pandemic as key contributors to increased logistics costs in the Brazilian public health system. This scenario highlights the need to incorporate emerging technologies, such as artificial intelligence and machine learning, to predict market fluctuations and optimize inventory control, as suggested by Riley et al.¹⁴ In their study, the authors emphasized the role of predictive analytics in enabling real-time decision-making and improving stock accuracy, especially in volatile contexts. Blockchain technologies have also been proposed to enhance traceability and transparency in pharmaceutical supply chains, contributing to minimizing losses¹⁵. These tools, coupled with green innovations such as those outlined by Xue et al.¹¹ - who explored sustainable logistics frameworks capable of reducing environmental impact through circular practices and digital traceability - may not only mitigate financial losses but also promote environmental sustainability. For instance, integrating blockchain and AI-based systems in pharmaceutical logistics could improve waste tracking, contributing to reductions in carbon footprint and aligning operations with sustainability goals.

However, although the benefits of these technologies are acknowledged, the study did not propose a concrete roadmap for their implementation. A critical discussion of potential barriers—such as high initial investment costs, interoperability limitations with existing systems (e.g., ERPs), regulatory constraints related to data security and traceability, and resistance to technological adoption by operational staff—would strengthen the argument and support strategic planning for future applications. Furthermore, implementation in resource-constrained environments, such as small and medium-sized pharmaceutical companies in peripheral regions, may require context-specific solutions and adaptive frameworks. Thus, pilot projects, capacity building, and public-private partnerships could represent viable mechanisms to overcome such barriers



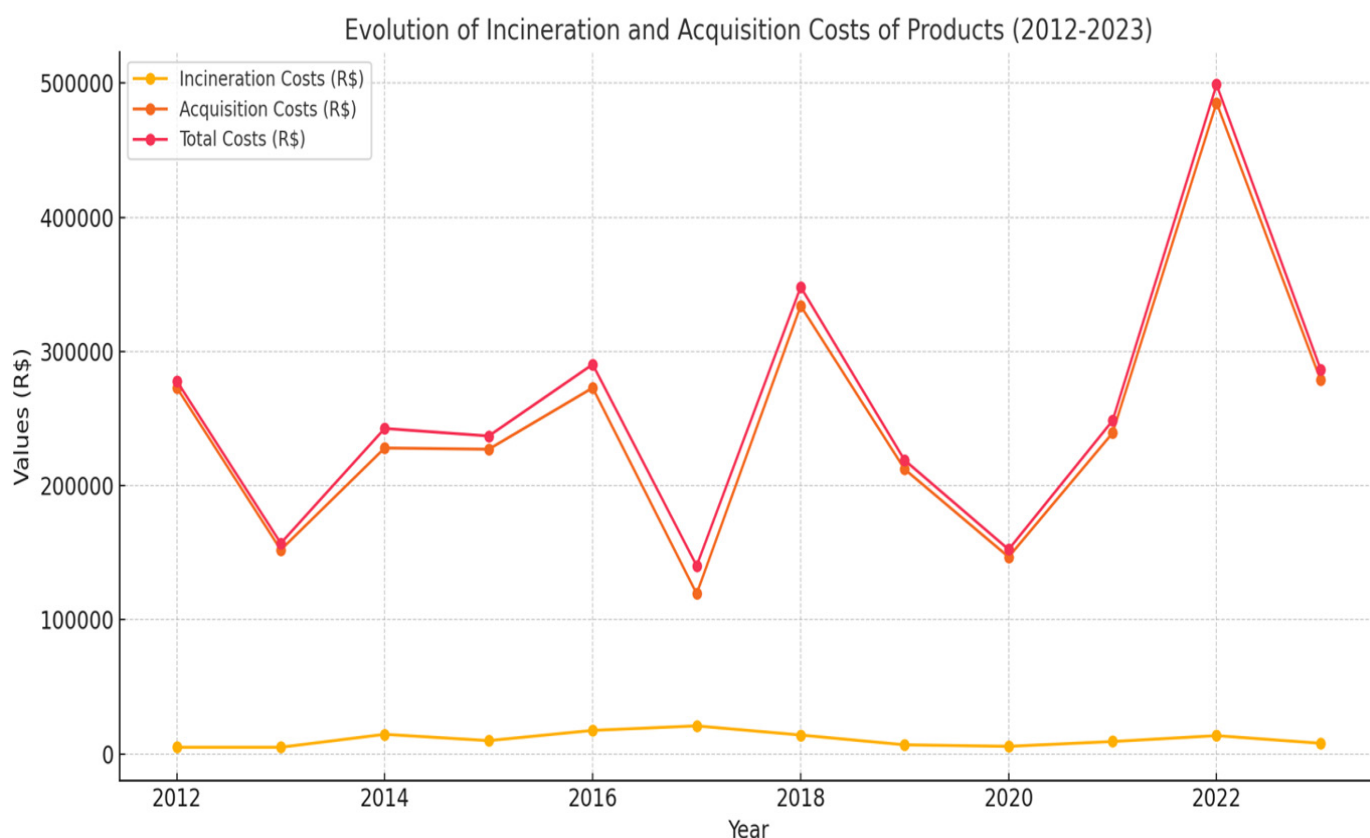


Figure 1. Evolution of Incineration and Acquisition Costs of Products (2012–2023).

and foster gradual incorporation of digital innovations into pharmaceutical logistics chains.

In addition to these technological perspectives, the statistical analysis revealed a Pearson correlation coefficient of 0.137 ($p = 0.671$) between incineration costs and acquisition costs, indicating no significant relationship between these variables. This result is relevant because it suggests that spending on incineration is not directly influenced by variations in acquisition costs, potentially reflecting inefficiencies in inventory management and waste disposal strategies. Such dissociation underscores the need for integrative approaches that jointly address procurement, storage, and disposal processes under a unified quality management framework. It also highlights the opportunity for improving decision-making based on real-time data, particularly through predictive analytics and system interoperability.

The qualitative analysis conducted using the Ishikawa Method was essential in identifying the root causes of financial losses. Among the main categories were inventory management problems (35%), inadequate commercial practices (25%), and logistical challenges (20%). These causes were directly related to the financial data, allowing for a more comprehensive interpretation of the results. For example, the absence of rotating inventories not only increased acquisition costs but also reduced supply chain efficiency,

reinforcing the importance of corrective actions such as training and process standardization^{16,17}. Additionally, sustainability-focused root causes, such as improper disposal methods and lack of environmental monitoring, could be addressed through the adoption of greener practices, as emphasized in studies by Zadrożny et al⁴.

While the findings reinforce existing literature, this study also addresses critical gaps. Few studies provide an 11-year longitudinal perspective on the impact of QMS, particularly in companies located in peripheral regions of global markets, such as the Brazilian Amazon. The integration of quantitative and qualitative results offers a robust foundation for replicating strategies in smaller companies or those with limited resources¹⁸. Furthermore, the results highlight the central role of the pharmacist as a logistics manager and transformation agent in the supply chain, an aspect rarely explored in previous studies¹⁹. The inclusion of pharmacists in sustainability-focused logistics could further enhance their role in aligning operational efficiency with environmental responsibility, as highlighted in green innovation frameworks¹¹.

However, methodological limitations that may have influenced the results are acknowledged. The exclusive reliance on data generated by the Protheus system may introduce biases, particularly concerning traceability and record quality. Moreover, the impact of external factors, such as regulatory

changes and economic fluctuations, was not fully isolated, limiting the interpretation of findings in certain periods²⁰. Future studies could include comparative analyses with companies of different sizes or sectors and incorporate data from multiple sources to minimize biases and broaden the applicability of the results²¹. Additionally, studies incorporating spatial econometric analyses could provide insights into regional variations and their influence on logistical practices, as demonstrated by Li et al¹⁰.

The practical implications of this study are significant. Beyond reinforcing the importance of QMS in reducing losses, the findings suggest that adopting emerging technologies, such as predictive systems based on artificial intelligence, can transform logistics management in the pharmaceutical sector, particularly in scenarios of high uncertainty²². The integration of sustainable practices, such as reducing pharmaceutical waste through more efficient controls, also contributes to alignment with global sustainability goals²³. Furthermore, green innovations and ESG-focused strategies could enhance operational efficiency while addressing environmental concerns, reinforcing the need for a comprehensive approach to logistics management in the pharmaceutical sector⁴.

CONCLUSION

This study demonstrated the significant financial impact of incineration and acquisition of expired and damaged pharmaceutical products, totaling BRL 3,097,950.75 between 2012 and 2023. The implementation of the QMS proved to be an effective strategy in reducing financial losses through actions such as rotating inventories, staff training, and process standardization, resulting in improved traceability and operational efficiency. However, the

COVID-19 pandemic highlighted vulnerabilities in the supply chain, emphasizing the need for resilience-focused policies and advanced technologies, such as artificial intelligence and blockchain, to enhance predictive capabilities and transparency. While the findings reinforce the relevance of QMS in logistical management, limitations include the focus on a single organization and the lack of broader contextual analysis. Future studies should explore diverse contexts and integrate emerging technologies to optimize inventory control and minimize losses. This study also reaffirms the pharmacist's critical role as a logistics manager, contributing to sustainable practices that align with global sustainability goals by reducing pharmaceutical waste and improving environmental outcomes. The results underscore the need for continuous efforts to enhance sustainability and efficiency in the pharmaceutical sector, contributing to more resilient supply chains and supporting economic and environmental goals.

AUTHOR CONTRIBUTION

The study was conceptualized by LWPS, CHMAR and JLFV. AGNCM and MPMS contributed to methodology, investigation, data curation, formal analysis of quantitative and qualitative data, validation, visualization, writing of the original draft, review, and editing. BCBA, UGA and GATC contributed to methodology, investigation, formal analysis of qualitative data, visualization, writing of the original draft, review, and editing. JLFV, LWPS, MPMS, CAS, CHMAR and BCBA contributed to the validation, visualization, revision and editing of the manuscript. LWPS contributed, methodology, supervision, validation, visualization, review, and editing.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest to disclose.

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