

**STANDARD OPERATING PROCEDURES: A PROPOSED FRAMEWORK FOR
MANAGEMENT AND IMPLEMENTATION*****PROCEDIMENTOS OPERACIONAIS PADRÃO: PROPOSTA DE UM FRAMEWORK
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ABSTRACT

Objective: The objective of this article is to analyze the applicability, benefits, and challenges of Standard Operating Procedures (SOPs) in different organizational contexts, proposing a framework for their implementation, management, and adaptation. **Theoretical framework:** The research is based on literature regarding process standardization, operational efficiency, regulatory compliance, and innovation. It addresses the contributions of SOPs to organizational stability and the challenges related to resistance to change, administrative complexity, and the need for constant updates. **Methodology/Approach:** The study adopted an exploratory and descriptive approach, based on a systematic literature review (SLR). A total of 58 scientific articles were analyzed to identify evidence on the implementation, management, and effectiveness of SOPs. The findings were categorized into five main themes, which serve as the foundation for the development of the proposed framework. **Results:** The results indicate that SOPs play a key role in reducing variability, increasing predictability, and fostering organizational innovation. However, their adoption faces challenges such as employee resistance and the need for continuous adaptation. The proposed framework provides guidelines to overcome these barriers and maximize the benefits of SOPs, allowing their application across different sectors. **Contributions, Practical and Social Implications:** This article presents a structured model to facilitate the implementation and management of SOPs, contributing to improvements in operational efficiency, regulatory compliance, and innovation. It also provides insights for managers seeking to optimize processes and promote greater organizational engagement, ensuring business sustainability and competitiveness. **Originality/Value:** The value of this study lies in consolidating practices and challenges related to SOPs into an adaptable framework, addressing the lack of systematic guidelines for their continuous management. The proposed approach enhances flexibility in the application of these procedures, balancing standardization and innovation, and making the model relevant for various organizational contexts. **Keywords:** Standard Operating Procedures. Operational Efficiency. Regulatory Compliance. Quality. Organizational Innovation

RESUMO

Objetivo: O objetivo deste artigo é analisar a aplicabilidade, os benefícios e os desafios dos Procedimentos Operacionais Padrão (POPs) em diferentes contextos organizacionais, propondo um framework para sua implementação, gestão e adaptação. **Referencial Teórico:** A pesquisa fundamenta-se na literatura sobre padronização de processos, eficiência operacional, conformidade regulatória e inovação. São abordadas as contribuições dos POPs para a estabilidade organizacional e os desafios relacionados à resistência à mudança, à complexidade administrativa e à necessidade de atualizações constantes. **Metodologia/Abordagem:** O estudo adotou uma abordagem exploratória e descritiva, baseada em uma revisão sistemática da literatura (RSL). Foram analisados 58 artigos científicos para identificar evidências sobre a implementação, gestão e eficácia dos POPs. Os achados foram categorizados em cinco eixos principais, servindo de base para o desenvolvimento do framework proposto. **Resultados:** Os resultados indicam que os POPs desempenham um papel essencial na redução da variabilidade, no aumento da previsibilidade e no incentivo à inovação organizacional. No entanto, sua adoção enfrenta desafios, como resistência dos colaboradores e necessidade de adaptação contínua. O framework proposto estrutura diretrizes para superar essas barreiras e maximizar os benefícios dos POPs, permitindo sua aplicação em diferentes setores. **Contribuições, implicações práticas e sociais:** O artigo oferece um modelo estruturado para facilitar a implementação e gestão dos POPs, contribuindo para a melhoria da eficiência operacional, da conformidade regulatória e da inovação. Também fornece subsídios para gestores que buscam otimizar processos e promover maior engajamento organizacional, garantindo a sustentabilidade e a competitividade das empresas. **Originalidade/Valor:** O valor do estudo reside na consolidação de práticas e desafios relacionados aos POPs em um framework adaptável, suprimindo a lacuna de diretrizes sistemáticas para sua gestão contínua. A proposta possibilita maior flexibilidade na aplicação desses procedimentos, equilibrando padronização e inovação, o que torna o modelo relevante para diferentes realidades organizacionais.

Palavras-chave: Procedimentos Operacionais Padrão. Eficiência Operacional. Conformidade Regulatória. Qualidade. Inovação Organizacional.

Introduction

Efficiency and quality in internal processes are key determinants of organizational performance, especially in sectors subject to strict regulatory requirements and high competitiveness (Metz et al., 2020). Standard Operating Procedures (SOPs) are strategic tools that establish clear guidelines for task execution, reducing variability and optimizing operations (Khairunnisa et al., 2020). In addition to ensuring regulatory compliance, SOPs strengthen organizational stability and promote continuous improvement, which are fundamental aspects of long-term business sustainability (El-Khalil et al., 2020).

Process standardization is widely adopted in industries such as pharmaceuticals, manufacturing, and healthcare services, where precision and reproducibility are essential for ensuring quality and safety (Hollmann et al., 2020). Its application also extends to administrative areas, including human resource management, financial control, and customer service (Ribeiro, 2020). In these contexts, SOPs enhance productivity, ensure service quality, and facilitate the integration of new employees—particularly relevant for organizations experiencing high staff turnover or rapid growth (Kadir, 2021). Structuring workflows and reducing variability also promote operational consistency and support internal and external audits, reinforcing corporate governance (Engkus, 2023; Maritan et al., 2024).

Despite these benefits, implementing SOPs poses significant challenges. Standardization is often perceived as limiting employee autonomy, leading to resistance and hindering adoption (Kalenda et al., 2018). In addition, the need for frequent updates to keep procedures aligned with regulatory, technological, and operational changes increases the complexity of SOP management (Urbinati et al., 2020). Without a structured model to guide these adaptations, procedural effectiveness tends to decline over time.

Although SOPs are traditionally associated with reducing variability, they can also support innovation. Well-structured processes reduce the burden of repetitive operational tasks, enabling employees to focus on process improvement and strategic initiatives (Lindsay et al., 2017). This balance between stability and innovation can offer a competitive advantage to organizations seeking efficiency and adaptability.

The literature extensively discusses the benefits and challenges of SOPs. However, most studies remain focused on isolated aspects, such as regulatory compliance or operational efficiency, lacking an integrated approach to issues such as resistance to change, the need for continuous updates, and the tension between standardization and innovation. Moreover, recent

advancements in organizational practices and digital process management are not yet fully addressed by the current body of research. This reinforces the need to revisit the state of the art and propose new approaches.

In this context, this study goes beyond conducting a systematic literature review (SLR). It integrates and expands the fragmented knowledge on SOPs into a comprehensive and adaptable framework that addresses current implementation and management challenges. By organizing recent evidence (2015–2025), we present a dynamic model that guides organizations in optimizing operational efficiency, fostering innovation, and ensuring regulatory compliance through structured, flexible practices.

The proposed framework not only systematizes best practices for SOP adoption but also offers a dynamic model to address challenges, such as resistance to change, administrative complexity, and the need for continuous adaptations, identified in the SLR. By deepening the relationship between standardization and innovation, this study demonstrates how structured processes can enhance an organization's capacity for continuous improvement.

This article is structured into sections that present the theoretical foundation on SOPs, the methodology used in the SLR and framework development, the presentation and analysis of key results, and, finally, a discussion of the study's implications, followed by conclusions and suggestions for future research.

Literature Review

Process standardization has been widely studied as a mechanism to enhance efficiency, ensure regulatory compliance, and promote continuous improvement in organizations. Different approaches and sectors adopt SOPs to structure activities, reduce variability, and facilitate audits. To understand the fundamentals of this practice, the next section discusses its role in organizational management, its impact on quality and efficiency, and the challenges associated with its implementation.

Process standardization in organizations

Process standardization is essential for operational efficiency, variability reduction, and regulatory compliance (Rebelo et al., 2016; Reif et al., 2019). SOPs structure routine activities, integrate new practices and technologies, and enable organizations to operate competitively in

highly regulated markets (Kong et al., 2022; Hollmann et al., 2020). In addition to ensuring quality, they reduce operational errors and enhance traceability, making processes more predictable and secure (Kasiri et al., 2017; Situmorang et al., 2022).

The studies of Arciniegas (2019) and Rodríguez-Pérez (2018) link standardization to quality and regulatory compliance, underscoring its role in deviation correction, enhancing audit efficiency, and promoting corporate transparency. Beyond these regulatory aspects, its implementation also reinforces organizational culture by fostering discipline and strengthening workplace safety, elements that contribute to talent retention and increased employee satisfaction (Khairunnisa et al., 2020).

Although traditionally associated with variability reduction, SOPs also drive organizational innovation. Well-structured processes create an environment conducive to incremental innovation and continuous improvement (Zoo et al., 2017; Mentel & Hajduk-Stelmachowicz, 2020). Clear procedures facilitate the integration of new technologies without compromising operational efficiency, balancing stability and adaptability (Ball & Lunt, 2020; Cerezo-Narváez et al., 2019). Thus, in addition to ensuring quality and compliance, SOPs support organizational learning and the evolution of internal processes (Rebelo et al., 2017).

However, the application of SOPs varies across countries and sectors, influenced by regulatory, cultural, and industrial factors (Abbott & Snidal, 2021; Reif et al., 2019).

Global implementation of SOPs: regulatory and cultural variations

The adoption of SOPs varies across countries due to regulatory differences and organizational approaches. In some regions, guidelines are strictly enforced, whereas in others, there is greater flexibility to adapt to business needs (Situmorang et al., 2022). These variations reflect efforts to balance local requirements with global standards, as observed in the European Union, the United States, Japan, and China.

In the European Union (EU), SOPs are widely applied in industries such as pharmaceuticals, food production, and medical devices, where compliance with strict regulations is essential. In the food sector, Regulation (EC) No. 853/2004 establishes general hygiene standards, requiring operators to meet specific requirements at all stages of food production, processing, and distribution (EUR-Lex, 2004).

In the pharmaceutical industry, Good Manufacturing Practices (GMP) ensure the quality and safety of medicines. The European Medicines Agency (EMA) coordinates inspections and

harmonizes the application of these guidelines across the EU, ensuring that medicines meet quality and safety requirements (EMA, 2020).

In the United States, the Food and Drug Administration (FDA) enforces stringent regulations known as Current Good Manufacturing Practice for the pharmaceutical industry, requiring companies to ensure the quality, safety, and efficacy of their products (FDA, 2024a). Despite strict regulations, companies are responsible for adjusting internal processes to incorporate new technologies and respond to market changes, provided they maintain accurate documentation and internal accountability (FDA, 2024b). This flexibility allows a balance between compliance and innovation.

In Japan, the integration of standardized procedures with the Kaizen philosophy is fundamental to continuous organizational improvement. The Toyota Production System (TPS) exemplifies this approach by using standardized procedures to ensure uniform and efficient execution of each production stage (Wada, 2020). This standardization facilitates the identification of deviations and improvement opportunities, encouraging active worker participation in suggesting enhancements. As a result, TPS not only increases efficiency but also reduces waste, making processes leaner and more productive (Cerezo-Narváez et al., 2019; El-Khalil et al., 2020).

In China, substantial reforms have been implemented to improve regulatory standards and align them with international practices, particularly in the pharmaceutical industry. In 2010, the revision of GMP guidelines incorporated principles from the International Council for Harmonization Q9 and Q10 guidelines, emphasizing quality risk management and a systematic approach to ensuring quality throughout the manufacturing process (Rodríguez-Pérez et al., 2014).

The updated GMP standards aim to align China's pharmaceutical manufacturing with global benchmarks, enhancing product quality and safety (WHO, 2017). The National Medical Products Administration has played a central role in implementing these guidelines, conducting inspections and certifications to ensure compliance and protect public health (Balzano, 2024).

A comparison of these different contexts highlights that, although SOPs share the common goal of ensuring quality and compliance, their implementation varies according to the regulatory and cultural requirements of each region. While the EU emphasizes strict oversight, the US adopts a more flexible approach that fosters innovation. In Japan, operational efficiency and continuous improvement are priorities, whereas in China, alignment with international standards has been the main strategy. These differences reinforce the need to adapt SOPs to

local specificities to ensure global competitiveness.

Impacts of SOPs on organizational efficiency and innovation

The pursuit of operational efficiency and process consistency has made standardization a central element of organizational structure. Its systematization enables the precise execution of activities, particularly in highly regulated sectors such as the pharmaceutical and aerospace industries, where strict compliance with standards is required to ensure quality and safety (Hollmann et al., 2020). The adoption of these procedures reduces variability, improves predictability, and supports compliance with regulatory and industrial standards (Bonnín Roca et al., 2017; Kasiri et al., 2017).

Standardization also plays a strategic role in fostering continuous improvement. According to Khosroniya et al. (2024), its adoption generates gains in product quality, operational efficiency, and cost reduction related to rework. Well-structured processes reduce failures and increase consistency, improving customer satisfaction and strengthening competitiveness (Kasiri et al., 2017; Situmorang et al., 2022).

Documenting processes clearly aligns teams by ensuring that all employees understand their responsibilities and the required standards. This reduces misunderstandings and the need for constant supervision, allowing managers to focus on strategic priorities such as innovation and market expansion (Sithambaram et al., 2021).

In administrative areas such as human resource management, financial control, and customer service, process standardization accelerates learning, facilitates the onboarding of new employees, and improves operational traceability, ensuring transparency and regulatory compliance (Soliani et al., 2024a; Jalundhwala & Londhe, 2023). It also contributes to flexibility by preparing teams for operational changes and reducing inconsistencies (Soliani et al., 2024b; Khairunnisa et al., 2020).

International certifications such as ISO 9001 and Six Sigma demand strict process control and robust documentation. ISO 9001:2015 establishes quality management guidelines to meet stakeholder expectations, while Six Sigma aims to reduce variation and defects, improving the reliability of products and services (Barbosa et al., 2022; Patel & Patel, 2021).

Although often associated with rigidity, standardization also supports incremental innovation and continuous improvement (Zoo et al., 2017; Mentel & Hajduk-Stelmachowicz, 2020). Structured processes reduce uncertainty, enabling resource reallocation toward

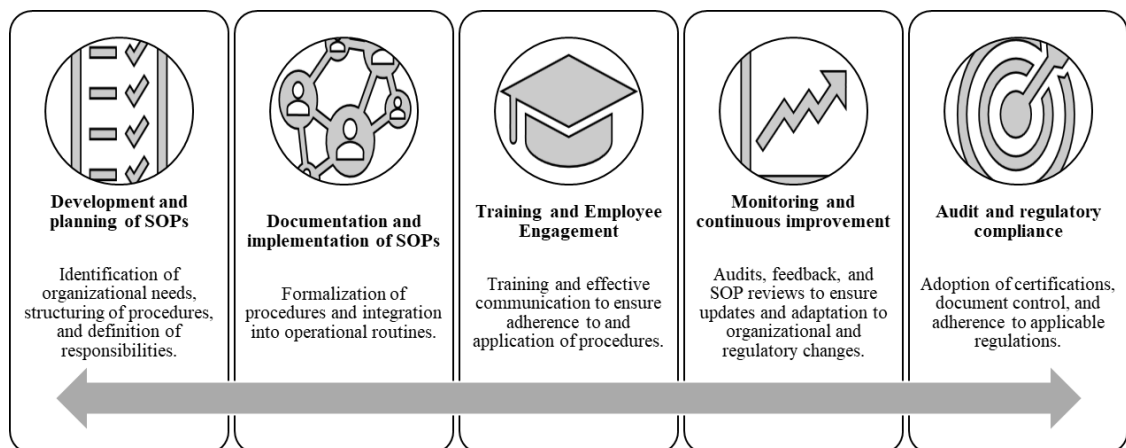
controlled improvements and the integration of new technologies without compromising efficiency (Ball & Lunt, 2020; Cerezo-Narváez et al., 2019).

In risk management, SOPs promote predictability and early failure detection by establishing clear operational parameters (Folch-Calvo et al., 2020). They also allow the controlled testing of new ideas, helping to ensure strategic alignment before full implementation (Panayiotou et al., 2022).

Figure 1 presents a conceptual model developed from the literature review, organizing the stages of SOP implementation and application. It summarizes how standardization contributes to operational optimization and supports continuous improvement across different organizational contexts.

Figure 1

Conceptual model of the implementation and application stages of SOPs.



Note. Authors (2025).

Effective process standardization depends on a structured, participatory approach. As emphasized by Herrera (2016), involving multiple stakeholders ensures that procedures are aligned with organizational needs and promotes a culture of shared responsibility. Furthermore, updating SOPs regularly is essential for maintaining their effectiveness in light of regulatory, technological, and market changes (Chakkol et al., 2018).

Beyond a set of rules, standardization structures reliable, efficient operations aligned with compliance requirements. Its application fosters a culture of continuous improvement and innovation, enhancing organizational reputation and attracting stakeholders who value safety and quality (Soliani et al., 2021). Thus, SOPs represent a strategic tool for sustainable organizational performance across diverse contexts.

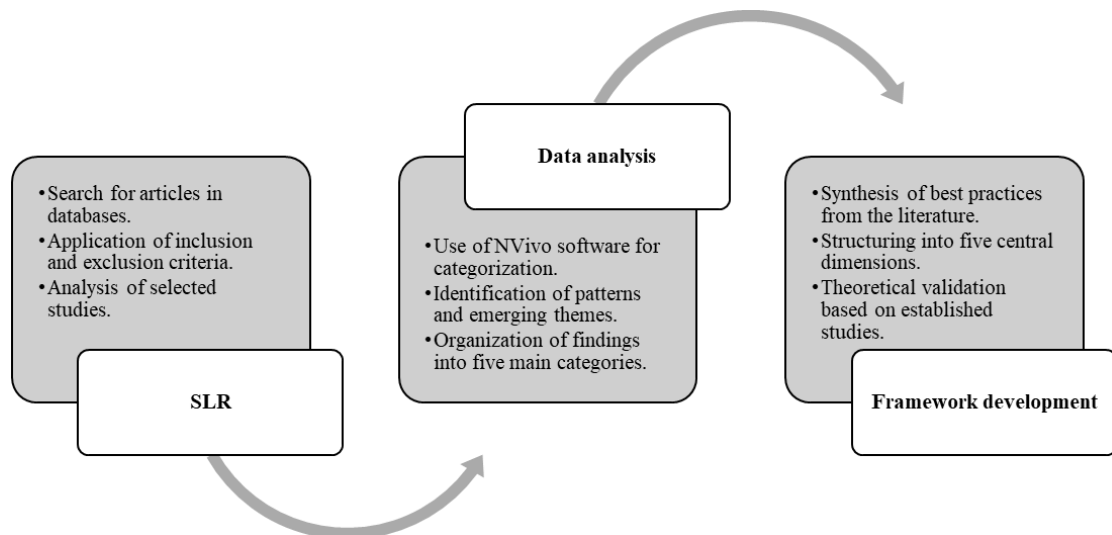
METHODOLOGY

To investigate the applicability and usefulness of SOPs in different organizational contexts, we conducted a SLR, followed by the development of a practical framework. The goal of the SLR was to identify and systematize scientific evidence on the implementation, management, and effectiveness of SOPs, mapping challenges, benefits, knowledge gaps, and best practices. These findings served as the foundation for constructing a framework to guide the adoption, adaptation, and continuous management of SOPs, aiming to optimize efficiency, foster innovation, and promote sustainability across sectors.

The research followed an exploratory and descriptive approach. The exploratory component focused on identifying and organizing existing evidence in the literature, while the descriptive component involved the detailed analysis of practices and the structured formulation of the framework. The methodological flow is presented in Figure 2.

Figure 2

Methodological flow.



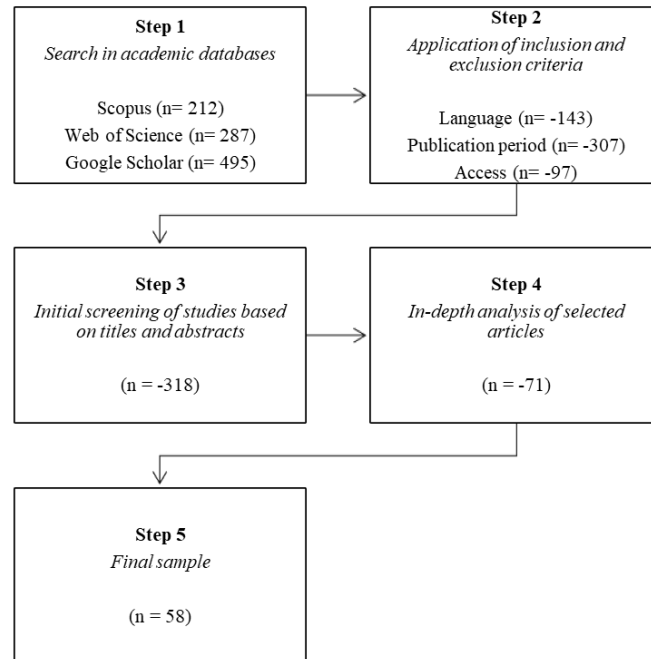
Note. Authors (2025).

The review followed the methodological guidelines of Gonzales-Gemio et al. (2020), ensuring rigor and transparency at all stages. Inclusion and exclusion criteria were defined to ensure the relevance, quality, and timeliness of the data. Only peer-reviewed articles published between 2015 and 2025 were included, as this period reflects recent advances and trends in

SOP research. Eligible studies were required to be in English or Portuguese and to address the implementation, management, or effectiveness of SOPs, with an emphasis on efficiency, innovation, or sustainability.

To ensure the applicability of the findings, empirical studies or systematic reviews that included relevant keywords in the title, abstract, or main text were indexed in recognized databases, and organizational contexts that were analyzed were selected. Articles that did not address SOPs in an organizational context, such as clinical or military protocols, as well as purely theoretical studies without practical application or empirical evidence, were excluded. Duplicate publications and articles without full-text access were also discarded.

The search was conducted in the Scopus, Web of Science, and Google Scholar databases, using structured keyword combinations such as: “Standard Operating Procedures” AND “organizational efficiency” OR “process improvement”; “Procedimentos Operacionais Padrão” AND “innovation management” OR “continuous improvement”; and “SOPs” AND “process standardization” OR “organizational adaptation.” The study selection followed three sequential stages. Initially, titles were screened for a preliminary selection, followed by an abstract evaluation to exclude studies that did not meet the established criteria. Finally, a full-text review ensured the relevance of the included material. To expand the scope of the review, the snowball sampling technique was applied, allowing the inclusion of articles cited in the most relevant studies but not identified in the initial search. The inclusion and exclusion process is summarized in Figure 3.

Figure 3*Article selection and screening process.**Note.* Authors (2025).

The initial search resulted in 994 articles, with 312 from Scopus, 287 from Web of Science, and 395 from Google Scholar. After applying the language criterion, 143 articles were eliminated. Another 307 were excluded for not meeting the established publication period, and 97 were removed due to unavailability of the full text, leaving 447 studies for analysis. The initial screening of titles and abstracts led to the exclusion of 318 articles that were not aligned with the topic or did not meet the inclusion criteria. In the final stage of full-text review, 71 studies were discarded for lacking empirical data or failing to meet the defined methodological requirements, resulting in a final sample of 58 articles for the systematic review. This final set of articles served as the basis for data extraction and thematic analysis, as detailed in the following section.

Data analysis

Data extraction and analysis were conducted systematically, focusing on elements such as organizational context, research objectives, adopted methods, SOP implementation strategies, challenges faced, observed results, and contributions to practice and academia. The analysis was supported by NVivo software, which enabled the coding and organization of large

volumes of qualitative data.

The process began by fragmenting the content of each selected article into discrete units of meaning, specific findings, statements, or observations. These units were then examined for conceptual similarities. Through iterative axial coding, recurring patterns and related concepts were grouped into broader thematic clusters, allowing for the identification of central themes consistently addressed across the studies.

Five main categories emerged from this process, based on the frequency of their appearance and relevance to SOP management: operational efficiency, linked to variability reduction, resource optimization, and process predictability; product and service quality, related to standardization for consistency and customer satisfaction; regulatory compliance, focused on adherence to legal requirements and audit facilitation; organizational challenges, covering resistance to change and administrative complexity; and engagement and training, addressing the role of employee involvement and development in ensuring effective SOP application.

Framework development

The development of the framework followed the methodological guidelines of Li (2020) and was grounded in the findings from the SLR, unfolding in three main stages. First, best practices and strategic recommendations from the selected studies were systematically synthesized to define core principles for the implementation and management of SOPs. This step ensured that the framework was evidence-based and aligned with the literature.

Second, the framework was organized around five key process dimensions—organizational diagnosis, strategic planning, development and documentation, implementation and training, and continuous monitoring and improvement. These stages were derived from recurrent operational challenges and enabling factors identified through axial coding in NVivo. Each component was detailed to ensure logical progression, internal consistency, and applicability across diverse organizational environments.

Third, a theoretical validation was performed through critical cross-analysis of the literature, verifying alignment between the framework structure and the conceptual models adopted in the reviewed studies. This step ensured the robustness and adaptability of the framework to different regulatory, technological, and sectoral contexts.

RESULTS

With increasing regulatory complexity and the demand for greater operational predictability, process standardization plays a strategic role in organizational management. The SLR consolidated evidence on the implementation, management, and effectiveness of SOPs, highlighting their applicability across different organizational contexts. To support the formulation of the proposed framework, the findings were structured according to the key contributions of each selected study, as presented in Table 1.

Table 1

Main contributions of the articles included in the SLR.

Author	Main Contribution
Abbott et al. (2021)	Conceptualizes regulatory standard-setting as decentralized, competency-based bargaining among firms, NGOs, and states
Arciniegas (2019)	Analyzes legal compliance as a tool for risk mitigation and corporate performance assurance
Ball & Lunt (2018)	Proposes a framework to integrate eco-efficiency and innovation in lean operations
Balzano (2024)	Analyzes product regulation in pharmaceutical and cosmetic sectors in China from comparative perspectives
Barbosa et al. (2022)	Systematizes lessons learned from ISO 9001:2015 implementation in Brazilian industrial companies
Barenji et al. (2024)	Proposes an integrated system to improve quality and consistency under the Pharma 4.0 philosophy
Bonnín Roca et al. (2017)	Introduces an adaptive regulatory model for emerging technologies in critical safety sectors
Cabri & Fioretti, 2022	Proposes a unifying framework showing that standardization enables flexibility in diverse organizational forms
Cerezo-Narváez et al. (2019)	Presents the implementation of an R&D+i management system in an SME for innovation and competitiveness
Chakkol et al. (2018)	Explores the role of collaboration standards in complex projects and their contractual influences
El-Khalil et al. (2020)	Relates stability, standardization, and continuous improvement in lean management systems
Engkus (2023)	Redefines public service with a focus on interagency coordination and government efficiency
Fiorello et al. (2023)	Links Industry 4.0 technologies to the evolution of lean-green practices in manufacturing companies
Folch-Calvo et al. (2020)	Analyzes risk assessment methodologies in industrial parks to prevent domino effects
Herrera (2016)	Proposes an innovation framework that balances corporate performance and social impact
Hole et al. (2021)	Examines challenges and solutions for digitizing processes in the pharmaceutical industry

Hollmann et al. (2020)	Proposes a standardized workflow to ensure reproducibility and transparency in research
Jalundhwala & Londhe (2023)	Outlines an operational excellence model for regulatory compliance in the pharmaceutical industry
Kabeyi (2019)	Discusses strategic management as a tool to improve competitiveness and corporate governance
Kadir (2020)	Analyzes the impact of SOPs, internal control, and workload on employee performance
Kalenda et al. (2018)	Explores practices and challenges for scaling agile methodologies in large organizations
Kasiri et al. (2017)	Links standardization and customization to service quality and customer loyalty
Khairunnisa et al. (2020)	Proposes integrated SOPs for audits in management systems to improve organizational efficiency
Khanzada (2024)	Highlights conformity assessment's role in ensuring quality and compliance in the context of Industry 4.0
Khosroniya et al. (2024)	Analyzes the impact of Industry 4.0 on quality management and total productive maintenance
Kong et al. (2022)	Investigates how service standardization affects financial outcomes and well-being in nursing homes
Kontogiannis et al. (2017)	Proposes total safety management principles integrated into organizational management systems
Kotsanopoulos & Arvanitoyannis (2017)	Examines food safety audits and quality standards in the global food sector
Kumar & Bhatia (2021)	Demonstrates that environmental dynamism drives Industry 4.0 adoption, improving performance through mediating factors
Lindsay et al. (2017)	Highlights the impact of collaborative innovation in public services, such as NHS pharmacies
Lorenz et al. (2019)	Explores standardization as a mechanism to integrate research and development in biotechnology
Maritan et al. (2024)	Proposes a framework to implement an innovation hub driving regional development and industrial competitiveness
Mentel & Hajduk-Stelmachowicz (2020)	Links ISO certifications to innovation in European countries
Metz et al. (2020)	Analyzes the impact of organizational culture on customer service effectiveness
Mokogwu et al. (2024)	Proposes a leadership model to develop operational policies in technology firms
Naidoo & Gasparatos (2018)	Examines corporate sustainability strategies in the retail sector and their environmental impacts
Panayiotou et al. (2022)	Implements Lean Six Sigma in manufacturing, proposing tools for small-scale projects
Patel & Patel (2021)	Analyzes the evolution of Lean Six Sigma and identifies critical success factors for its implementation
Pop et al. (2023)	Proposes an integrated approach to quality and process management in the aerospace industry
Rebelo et al. (2016)	Presents integrated management systems as tools for cleaner and more sustainable production
Rebelo et al. (2017)	Explores the integration of management systems to mitigate organizational risks
Reif et al. (2019)	Proposes a cyclical process management model to strengthen legitimacy and organizational effectiveness

Ribeiro (2020)	Presents foundational theories that support the evolution of management toward strategy and sustainability
Rodríguez-Pérez (2014)	Summarizes GMP principles to ensure drug quality, with practical guidance, standards, and audit tools
Rodríguez-Pérez (2018)	Addresses human error as a symptom of organizational issues and mitigation strategies
Sangwa & Sangwan (2018)	Develops a framework to measure lean performance across all organizational functions
Silva et al. (2020)	Proposes a sustainable management model integrated into management systems
Singh et al. (2023)	Proposes world-class quality practices to boost productivity in the Indian automotive industry
Sithambaram et al. (2021)	Identifies challenges and solutions for agile hybrid projects in the IT sector
Situmorang et al. (2022)	Analyzes the impact of SOPs and government policies on public satisfaction with quarantine services
Sjödín et al., 2021	Presents a framework for scaling AI in manufacturing through business model innovation and key capabilities
Soliani et al. (2021)	Reports the positive impact of a supplier development program in the sugar-energy sector
Soliani et al. (2024a)	Develops a competency framework for Industry 4.0 professionals
Soliani et al. (2024b)	Assesses the use of gamification as an educational tool for supply chain management
Urbinati et al. (2020)	Identifies how managerial actions enable digital technologies to support open innovation
Viardot et al. (2021)	Examines how standardization drives innovation and competitiveness in a digital and globalized economy
Wada (2020)	Examines the historical development of the TPS and its relation to digital technologies
Zoo et al. (2017)	Analyzes how standards facilitate innovation in developing countries

Note. Authors (2025).

The literature presents diverse perspectives on the implementation and management of SOPs across organizational settings. To consolidate this dispersed evidence and enable a structured interpretation, the findings were grouped into five thematic categories. These categories emerged from recurring patterns and conceptual convergence identified in the reviewed studies, reflecting the main dimensions through which SOPs influence organizational performance.

The thematic groups—operational efficiency, product and service quality, regulatory compliance, organizational challenges, and engagement and training—capture both the benefits and limitations associated with SOP practices. Table 2 summarizes these categories and their defining characteristics, serving as a conceptual bridge between the literature findings and the framework proposed in this study.

Table 2

Thematic groups identified in the SLR.

Theme	Description
Operational Efficiency	Refers to variability reduction, resource optimization, and increased process predictability, contributing to higher productivity and cost reduction
Product and Service Quality	Relates to uniformity in quality standards, ensuring that products and services meet or exceed customer expectations, fostering trust and loyalty
Regulatory Compliance	Concerns adherence to legal and regulatory requirements, facilitating audits, preventing penalties, and protecting organizational reputation
Organizational Challenges	Covers issues related to resistance to change, administrative complexity, and difficulties in the effective implementation and maintenance of SOPs
Engagement and Training	Highlights the need for continuous employee training and involvement to ensure adherence and effectiveness of SOPs

Note. Authors (2025).

The thematic categories presented synthesize how SOPs contribute to core organizational objectives, as evidenced by the literature. The theme of operational efficiency groups' studies linking SOPs to greater predictability, reduction of variability, and resource optimization, factors that support productivity and cost control. Product and service quality reflects the role of standardization in ensuring consistency and fostering customer satisfaction, which enhances trust and reliability (Kasiri et al., 2017). Regulatory compliance encompasses contributions highlighting SOPs as instruments for aligning internal procedures with legal and audit requirements, thereby mitigating risk and strengthening accountability (Rebelo et al., 2017).

In contrast, the organizational challenges theme highlights recurring barriers to SOP implementation, such as internal resistance, excessive bureaucracy, and the complexity of maintaining standardized practices over time (Kalenda et al., 2018). The theme of engagement and training includes findings emphasizing employee involvement and continuous learning as critical elements for ensuring effective and sustained use of SOPs (Mokogwu et al., 2024).

These thematic insights, derived from the systematic review, provide a structured understanding of the conditions under which SOPs are successfully adopted and maintained. This analytical basis supports the development of the framework proposed in the next section, which seeks to align standardization practices with strategic goals while addressing the practical constraints identified.

Proposed framework for the implementation and management of SOPs

The SLR revealed consistent patterns regarding the role of SOPs in organizational performance. As synthesized in Table 2, five thematic categories were identified: operational efficiency, product and service quality, regulatory compliance, organizational challenges, and engagement and training. These categories represent recurring strengths and limitations associated with SOP practices across different organizational contexts.

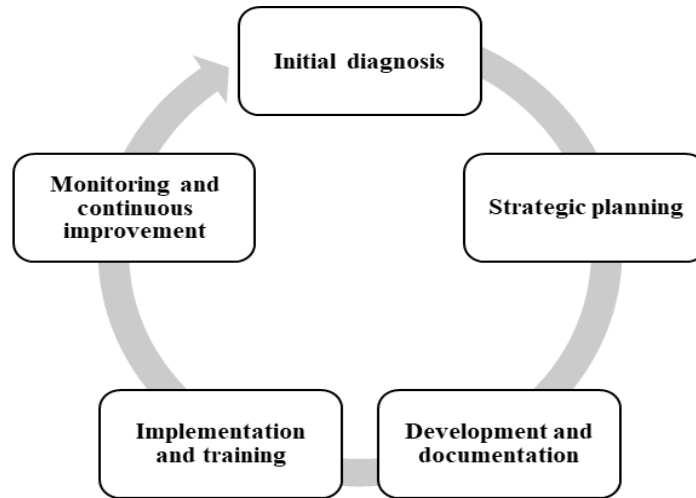
To transform this evidence into practical guidance, we conducted a second-level synthesis focused on the strategic and operational actions reported in the reviewed studies. Using axial coding in NVivo, we grouped these actions into five core process stages commonly described in the literature: organizational diagnosis, strategic planning, development and documentation, implementation and training, and continuous monitoring and improvement.

This synthesis informed the development of a structured framework that translates the literature's thematic findings into a sequential and iterative model for SOP implementation and management. Rather than presenting a generic step-by-step approach, the framework is grounded in empirical evidence and addresses the main constraints and enablers identified in the SLR. It was designed to overcome challenges such as resistance to change and administrative burden, while enhancing benefits related to efficiency, regulatory compliance, and continuous improvement. The framework's structure allows for cross-sectoral adaptation, enabling both standardization and contextualization.

Figure 4 presents the framework derived from the SLR findings, highlighting five interconnected stages and their iterative relationships.

Figure 4

Stages of the SOP management framework.



Note. Authors (2025).

The first stage, initial diagnosis, identifies operational gaps and specific needs within the organization. This mapping includes the analysis of existing processes, interviews with employees, evaluation of historical data, and direct observation of activities (Fiorello et al., 2023). This assessment allows the alignment of SOPs with recurrent issues highlighted in the literature, such as unclear procedures and low employee adherence.

The second stage, strategic planning, defines priorities, allocates resources, and establishes timelines for SOP creation and implementation. It also includes the assignment of responsibilities and alignment with organizational goals, promoting a structured and participatory approach (Kabeyi, 2019). This step mitigates fragmentation and resistance, making standardization more sustainable.

In the third stage, development and documentation, SOPs are created in a clear and objective manner suited to the operational context. Involving stakeholders ensures the procedures are applicable and avoids excessive bureaucratization or detachment from reality (Kontogiannis et al., 2017). In service contexts, the combination of standardization and customization enhances customer satisfaction.

The fourth stage, implementation and training, integrates SOPs into daily routines through structured training. Communicating the purpose and benefits of SOPs is central to overcoming resistance and encouraging engagement across organizational levels (Soliani et al., 2024a). In highly regulated sectors, this stage ensures compliance with standards and reduces operational risk.

Finally, the fifth stage, monitoring and continuous improvement, ensures SOPs remain effective and aligned with organizational, regulatory, and technological changes. Key performance indicators (KPIs) are established to evaluate efficiency, detect deviations, and support improvements (Sangwa & Sangwan, 2018). In industries such as automotive, audits of SOPs can reduce variability and improve product quality.

By integrating standardized procedures with adaptive flexibility, the proposed framework offers a comprehensive approach to SOP implementation and management that is both evidence-based and operationally feasible. It directly addresses the main limitations identified in the review—such as resistance to change and administrative burden—through structured and replicable processes.

Beyond process optimization, the framework strengthens transparency and accountability, reinforcing corporate governance and sustainability. Its modular structure facilitates adaptation across sectors and organizational maturity levels, positioning SOPs as strategic mechanisms for long-term competitiveness, resilience, and innovation.

DISCUSSION

The adoption of SOPs significantly impacts organizational management, extending beyond procedural standardization to influence efficiency, innovation, quality, and regulatory compliance (Reif et al., 2019). Analyzing both the benefits and challenges associated with SOP implementation underscores their role in structuring operations systematically and strengthening competitiveness in dynamic, highly regulated markets. Khanzada (2024) highlights that standardization not only enhances internal workflows but also improves risk management and compliance, particularly in industries that demand stringent audits and international certifications.

One of the most evident advantages of SOPs is enhanced operational efficiency. Standardization reduces process variability, improves predictability, and optimizes resource utilization, thereby directly increasing organizational productivity and profitability (Lorenz et al., 2019). In precision-driven industries, such as pharmaceuticals, chemicals, automotive, and aerospace, standardized processes contribute to shorter cycle times, error reduction, waste minimization, and improved product or service quality (Barenji et al., 2024; Hole et al., 2021; Pop et al., 2023; Singh et al., 2023). In the automotive sector, for example, standardization enhances production stability and process predictability, fostering greater integration across

operational units (El-Khalil et al., 2020).

Despite concerns that standardization may limit creativity, research suggests that well-structured processes can, in fact, drive innovation. Mentel and Hajduk-Stelmachowicz (2020) argue that clear operational guidelines create controlled environments for safely testing new ideas. This innovation-enabling effect is particularly evident in technology and service sectors, where standardization and customization coexist to ensure high quality while maintaining operational flexibility (Cabri & Fioretti, 2022). Moreover, integrating standardized methodologies with innovation strategies facilitates the adoption of emerging technologies and enhances organizations' agility in responding to market shifts (Viardot et al., 2021).

Another critical impact of SOPs is quality assurance. Well-implemented procedures ensure consistency in product and service delivery, reinforcing compliance with stringent quality standards and customer trust (Hollmann et al., 2020). This is particularly relevant in regulated industries such as pharmaceuticals and food production, where non-compliance can result in financial penalties and reputational damage (Jalundhwala & Londhe, 2023; Kotsanopoulos & Arvanitoyannis, 2017). Systematic audits and continuous monitoring are essential for sustaining SOP effectiveness and mitigating operational risks.

However, SOP implementation is not without challenges. Resistance to change and administrative complexity often hinder adoption and maintenance. Employees may perceive SOPs as bureaucratic constraints on autonomy. To mitigate such resistance, leadership must prioritize transparent communication, comprehensive training, and active workforce involvement in the SOP development process (Mokogwu et al., 2024). Periodic audits also play a critical role in identifying process inefficiencies and reinforcing compliance.

The continuous adaptation of SOPs is another pressing challenge, particularly as organizations navigate technological advancements, regulatory shifts, and evolving market demands (Kumar & Bhatia, 2021). Effective adaptation requires robust feedback mechanisms and digital tools to support real-time updates and procedural flexibility (Sjödín et al., 2021). In this context, adopting standardized management systems enhances governance and minimizes risks associated with non-compliance.

Beyond operational efficiency, SOPs significantly contribute to sustainability. Process optimization reduces resource consumption and waste generation, ensuring alignment with environmental regulations and corporate social responsibility goals (Silva et al., 2020). These practices enhance brand reputation and increase competitiveness, especially in global markets that emphasize environmental responsibility (Naidoo & Gasparatos, 2018).

Thus, SOPs serve as strategic tools that not only enhance efficiency but also enable innovation, quality assurance, compliance, and sustainability. However, their long-term success depends on adaptive implementation strategies. The proposed framework addresses this need by offering a structured, evidence-based methodology that enables organizations to manage SOPs dynamically, bridging the gap between standardization and strategic adaptability.

CONCLUSION

This article analyzed the applicability, benefits, and challenges of SOPs in contemporary organizations, highlighting their importance for operational efficiency, quality, regulatory compliance, and innovation. The systematic review demonstrated that, when well implemented, SOPs reduce variability, optimize resources, and support continuous improvement. However, challenges such as resistance to change, administrative complexity, and the need for constant updates require integrated strategies that combine effective communication, continuous training, and employee engagement to ensure long-term effectiveness.

The main scientific contribution of this study lies in the development of an evidence-based framework for SOP implementation and management. By synthesizing the literature into five strategic and operational stages, the model provides conceptual clarity and contributes to the academic understanding of standardization as a dynamic and adaptive process. This approach reinforces the theoretical link between procedural standardization and organizational resilience, positioning SOPs as enablers of innovation, governance, and long-term competitiveness.

From a practical standpoint, the framework offers a structured tool for guiding SOP practices, covering all phases from organizational diagnosis to continuous improvement. Its adaptability makes it relevant for highly regulated sectors, such as the pharmaceutical and food industries, where legal compliance is critical, as well as for service environments where process customization and customer satisfaction are priorities. By aligning procedures with strategic goals, the framework helps balance standardization and flexibility, supporting more resilient and sustainable management models.

Despite its contributions, this study presents some limitations. The framework is based exclusively on literature findings and has not yet been empirically tested. Contextual factors, such as organizational size, sector-specific regulations, and cultural variables, may influence its applicability. Additionally, the diversity of methodologies and conceptual approaches in the

reviewed studies may limit the generalizability of the thematic synthesis.

Future research should focus on the empirical validation of the framework in different organizational contexts and sectors. Longitudinal studies could assess the impact of SOPs on operational performance and innovation over time. Comparative studies between different standardization strategies could identify critical success factors, while qualitative approaches, such as interviews and case studies, may deepen understanding of organizational perceptions. Quantitative analyses using performance indicators and statistical models may also help evaluate the framework's effectiveness in enhancing efficiency, compliance, and governance.

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