Integrating 5S and Kaizen Principles for Enhanced Quality Improvement: A Pharmaceutical R&D Laboratory Case Study

DOI: 10.12776/qip.v28i3.2084

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Received: 2024-10-18 Accepted: 2024-11-06 Published: 2024-11-30

ABSTRACT

Purpose: This study aims to investigate the combined application of 5S and Kaizen methodologies in a pharmaceutical R&D laboratory to determine their impact on enhancing quality improvement processes and operational efficiency.

Methodology/Approach: The research adopted a single case study approach in a Greek pharmaceutical R&D laboratory. Quantitative data were gathered on deviations in analysis and experiment conduction times, while qualitative insights were derived from semi-structured interviews conducted with laboratory personnel before and after implementing the methodologies.

Findings: The study revealed significant improvements in laboratory operations following the implementation of 5S and Kaizen. Quantitatively, there was a notable reduction in analytical errors and experiment conduction times. Qualitatively, enhancements were observed in the workspace's organisation, equipment use efficiency, and employee engagement.

Research Limitation/Implication: Focusing on a single laboratory may not fully represent the diverse environments of other pharmaceutical R&D settings.

Originality/Value of paper: This paper contributes to the limited literature on using 5S and Kaizen in pharmaceutical R&D laboratories. It demonstrates the practical benefits of these methodologies in a highly regulated environment and provides a structured approach for their implementation.

Category: Case study

Keywords: quality improvement; 5S; kaizen; laboratory; pharmaceutical industry

Research Areas: Quality Management.

1 INTRODUCTION

Due to increasing global competition in the 21st century, quality has become crucial for business success. Heightened competition and growing customer demand for superior quality have prompted companies to prioritise the delivery of high-quality products and services (Al-Qudah, 2012). Over the past decades, organisations have adopted Total Quality Management (TQM) as a comprehensive strategy for quality improvement and operational excellence (Chountalas and Lagodimos, 2019). As industries evolve into the digital era, the concept of TQM also requires adaptation to align with Industry 4.0 technologies (Chiarini, 2020; Nguyen, et al., 2021; Souza, et al., 2021).

TQM is essential for pharmaceutical companies to establish business goals, strategies, culture, knowledge, and innovation across all organisational levels (Weitzel, et al., 2021; Qin, et al., 2022). Organisations employ various methodologies and tools to support this process, along with new technologies, with 5S and Kaizen being prominent examples (Islam, Samad and Islam, 2019; Haekal, 2023).

5S is recognised as a management method and a fundamental aspect of TQM, promoting an organised work environment that enhances quality and efficiency. Its implementation ensures that work areas are free from defects and interruptions, maintaining effective housekeeping (Oakland, 2014; Pačaiová and Ižaríková, 2019). The term 5S derives from five Japanese words: seiri, seiton, sesio, seiketsu, and shitsuke, which translate to sort, set in order, shine, standardise, and sustain (Kanamori, Shibanuma and Jimba, 2016). The primary framework for understanding and applying these principles was proposed by Takashi Osada (Jiménez, et al., 2015), although some attribute its development to Hiroyuki Hirano (Patel and Thakkar, 2014). Notably, Toyota was the first company to implement 5S principles (Jaca, et al., 2014).

Originating in Japan in the 1950s, Kaizen—meaning "continuous improvement"—emphasises the involvement of all organisational members, from managers to workers, in pursuing ongoing progress (Singh and Singh, 2015; Džubáková and Kopták, 2017). Western companies, seeking to understand Japan's industrial competitive advantage, recognised the Kaizen philosophy as a key factor for success. This approach later influenced manufacturing plants in North America, Europe, the United Kingdom, and Australia, leading to enhancements in production techniques, standardised operations, and increased employee contributions (Macpherson, et al., 2015).

The pharmaceutical industry, crucial to healthcare, adheres to strict regulations such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) to ensure product quality for disease diagnosis and treatment (Geijo, 2000; Mazumder, Bhattacharya and Yadav, 2011). Many companies are adopting methodologies like 5S and Kaizen to further enhance quality. Although these practices have been effectively implemented in healthcare settings, especially in hospitals (El-Sherbiny, Elsary and Ibrahim, 2017; Ishijima,

et al., 2020; Hammami, et al., 2022; Sallam, Allam and Kassem, 2024), their use in the pharmaceutical sector, whether separately or combined, is still in its early stages and mostly confined to production processes (Bevilacqua, et al., 2015; Sugiyama, Ito and Masahiko, 2015; Karam, et al., 2018; Haekal, 2023).

Pharmaceutical research and development (R&D) encompasses extensive chemical and biological processes essential for creating new drug formulations where maintaining high quality is crucial. The application of 5S and Kaizen methodologies can enhance these quality-centric procedures. For instance, Mallick, et al. (2013) showed how 5S supported regulatory compliance in laboratory settings. Despite the proven benefits of these methodologies, their synergistic application in pharmaceutical R&D remains underexplored. This study aims to bridge this gap by investigating how the combined use of 5S and Kaizen can significantly enhance quality in pharmaceutical R&D laboratories, underscoring the need for further research to fully utilise these methodologies.

The remainder of this paper is organised as follows: Section 2 first examines the separate implementation of 5S and Kaizen in the pharmaceutical sector and then explores how the combined application of these methodologies across various operational domains enhances their benefits. Section 3 describes the methodology of this study, including the research design and strategy, outlining how the single case study approach was employed. Sections 4 and 5 present the implementation and results of the case study, respectively. They discuss the quantitative and qualitative outcomes, highlighting significant improvements in processes and the workplace environment resulting from implementing 5S and Kaizen. Finally, Section 6 concludes the paper with a discussion of the research findings, emphasising the practical implications for continuous improvement in pharmaceutical laboratories and suggesting directions for future research.

2 BACKGROUND

2.1 Separate implementation of 5S and Kaizen in the pharmaceutical sector

Both 5S and Kaizen methodologies have been effectively implemented separately in the pharmaceutical sector, resulting in diverse impacts across various operational domains. Dixit, et al. (2019) demonstrated that 5S principles streamlined operations, enhanced safety, and improved drug product handling and storage in a large pharmaceutical warehouse in India. Similarly, Islam, et al. (2019) applied 5S across multiple departments in a pharmaceutical factory, resulting in faster task completion, better organisation, and a clutter-free environment. Mallick, et al. (2013) optimised the arrangement of chemical reagents and instruments in a pharmaceutical laboratory, thereby improving workflow. Moreover, Cherqaoui and Elhaq (2022) implemented 5S in a Moroccan pharmaceutical laboratory, leading to marked improvements in space efficiency

and workflow optimisation. Lestari, et al. (2022) integrated 5S into the operations of a quality control laboratory in Indonesia, significantly reducing task completion times by 42.7%.

In addition, Kaizen initiatives have led to substantial improvements. Kotvitska, et al. (2019) utilised Kaizen to improve the internal audit processes of a quality management system, thereby enhancing GMP compliance and quality awareness. Karam, et al. (2018) employed the SMED (Single-Minute Exchange of Die) Kaizen tool to effectively manage production line changeovers in the pharmaceutical industry, significantly reducing delays. Bellgran, et al. (2019) applied PDCA cycle principles to enhance manufacturing processes concerning environmental factors in a pharmaceutical company, resulting in cost savings and environmental benefits. Sugiyama, et al. (2015) implemented a five-step Kaizen methodology during pharmaceutical manufacturing, which reduced product losses and increased production yield. Furthermore, Haekal (2023) discussed the application of Six Sigma and Kaizen techniques in addressing non-conformities in the primary packaging processes of pharmaceutical products, demonstrating how these methodologies significantly reduced defects in paracetamol infusion products.

These examples indicate that while 5S and Kaizen are primarily applied in production and operational fields, their advantages are also evident in administrative and quality control areas, significantly contributing to efficiency and quality improvements within the pharmaceutical industry.

2.2 Combined implementation of 5S and Kaizen across several sectors

Case studies have illustrated the effectiveness of integrating 5S and Kaizen methodologies as tools for continuous improvement in various industries. Zadry and Darwin (2020) implemented these techniques in a shoe manufacturing company, successfully addressing defects related to methods, materials, equipment, and training, which resulted in a notable reduction in defects. Similarly, Aktar Demirtas, et al. (2023) applied 5S and Kaizen in a surgical mask manufacturing facility, leading to a cleaner and safer workplace, fewer production stoppages, increased output, improved product quality, and decreased customer complaints. Gupta and Jain (2014) conducted a case study on a small-scale manufacturing organisation, demonstrating how implementing 5S and Kaizen principles improved process visibility, enhanced employee morale and safety, and significantly reduced delays and hazardous conditions.

At South Dakota State University, Koromyslova, et al. (2018) utilised 5S and Kaizen in the Construction and Operations Management Department, resulting in reduced search times, fewer data entry errors, and accelerated onboarding processes for new members. Baptista, et al. (2021) examined the implementation of these methodologies in a Portuguese textile company facing rising orders and complex customer demands. By organising the company through 5S, employing

SMED to reduce production setup times, and enhancing interdepartmental communication, the company significantly minimised waste and improved quality.

Ishijima, et al. (2020) introduced the 5S-Kaizen-TQM approach in public hospitals in Egypt, successfully fostering improvements in quality management and operational efficiency across the health sector. Hammami, et al. (2022) also applied 5S and Kaizen in a public hospital in Tunisia, noting improvements in working conditions, optimised processes, and enhanced teamwork.

Studies on the combined implementation of 5S and Kaizen are scarce in the pharmaceutical sector. A notable exception is the work of Bevilacqua, et al. (2015), who applied both methodologies in a pharmaceutical company's production process. By employing SMED, Total Productive Maintenance (TPM), and 5S, their approach decreased changeover times and also led to a better-trained workforce, a more organised production line, and reduced downtime, ultimately enhancing productivity.

While numerous case studies highlight the benefits of 5S and Kaizen in enhancing workplace organisation, productivity, company culture, and safety, a significant gap exists in research regarding their synergistic impact within the pharmaceutical sector, especially outside of production environments.

3 METHODOLOGY

3.1 Research Design and Strategy

This study examines the impact of 5S and Kaizen continuous improvement techniques on workplace conditions, specifically regarding organisational culture and daily operations. A single case study methodology was employed to facilitate comprehensive observation and analysis (Voss, Tsikriktsis and Frohlich, 2002; Chountalas and Tepaskoualos, 2019).

The research was conducted at the analytical R&D laboratory of a Greek pharmaceutical company established in the late 1960s and focused on developing and producing pharmaceutical products. This laboratory is ISO 9001 certified and is structured with a vice president who establishes corporate objectives and quality policies, two managers overseeing analytical workloads and the implementation of quality standards, and twenty research scientists tasked with conducting analytical experiments and interpreting results.

The selection of this R&D laboratory was motivated by several factors, including the complexity of routine tasks that involve a variety of analyses, the handling of diverse samples such as active pharmaceutical ingredients (APIs), non-active raw materials, and lab-scale drug formulations, as well as the laboratory's willingness to embrace new ideas for workplace enhancements. The company permitted access to its R&D facilities, facilitating the study from September 2023 to July 2024.

Ten analytical R&D employees with backgrounds in chemistry, biology, and science engineering participated in the study on a voluntary basis, with a commitment to maintaining confidentiality regarding personal data. The research comprised quantitative and qualitative elements: four employees quantitatively measured the time taken to complete analytical experiments, while all ten participants contributed to the qualitative analysis by responding to seven questions before and after the interventions.

3.2 Quantitative Research

The aim of the quantitative research in this study is to assess the combined impact of the 5S and Kaizen methodologies on the processes within the pharmaceutical analytical laboratory under study. This includes a comparative analysis of quantitative data collected before and after implementing these methodologies.

Baseline data were initially collected from the laboratory's existing organisational records. Due to the laboratory's compliance with GLP and GMP, these records, which document analytical experiments, are consistently maintained and monitored to ensure data integrity.

Two key performance indicators (KPIs) were identified for this study. The first KPI, deviations in analysis, is divided into those attributed to human errors—likely due to poor organisation—and those caused by equipment malfunctions. To uphold confidentiality and avoid anti-trust issues, these deviations are anonymised and classified accordingly. Data on deviations were gathered from September 2023 to December 2023, prior to the interventions, and from January 2024 to April 2024, following the implementation of 5S and Kaizen.

The second KPI, experiment conduction time, involved monitoring four analysts, each with a minimum of two years of experience, as they performed three different types of experiments. The time required to complete these tasks was recorded twice: once before the implementation in November 2023 and once after in June 2024.

At the conclusion of the study, these quantitative metrics were analysed to evaluate the effects of the 5S and Kaizen interventions on enhancing laboratory efficiency and minimising errors.

3.3 Qualitative Research

To understand the perceptions of employees in the analytical R&D department regarding the implementation of 5S and Kaizen methodologies, qualitative research was conducted using semi-structured interviews with laboratory personnel both before and after the implementation of these methodologies. These interviews were structured around a questionnaire designed to capture employees' beliefs, practices, and feelings related to changes in their work environment.

The initial two questions of the questionnaire evaluated the cleanliness and organisation of the laboratory workspace. Prior research, such as Maharjan (2011), indicates that the application of the 5S methodology can significantly improve workspace cleanliness and organisation, thereby enhancing work efficiency. This aligns with findings from a university laboratory where the application of 5S resulted in better organisation and increased efficiency.

The third question assessed the reduction in time spent searching for equipment and experimental materials. Deshpande, et al. (2015) found that after implementing similar methodologies in the manufacturing sector, the time required to locate tools and materials was significantly reduced due to enhanced storage systems and identification controls.

The fourth question analysed the efficiency of analytical instrumentation, applying the Kaizen principle of TPM. Unlike most literature focusing on production equipment, this study emphasises analytical instrumentation, which is vital for achieving accurate analytical results. Setiawan (2021) noted that proper maintenance of these instruments can reduce breakdowns and improve outcome quality.

The final three questions investigated changes in employee engagement and corporate culture. These elements are essential, as implementing continuous improvement methodologies can substantially affect workplace culture and employee morale. According to Gunawan, et al. (2022), Kaizen methodologies not only enhance operational processes but also promote enthusiasm and a strong work ethic among employees, contributing to a positive shift in workplace culture.

4 CASE STUDY IMPLEMENTATION

4.1 Applying Kaizen and 5S methodologies in an analytical pharmaceutical laboratory

The integration of 5S and Kaizen methodologies can significantly improve organisational operations in various environments, including offices, production lines, and personal spaces. This research focuses on implementing a continuous improvement plan within a pharmaceutical company's analytical laboratory. Before applying these methodologies, a structured approach was established, outlining essential preparatory steps for successful implementation, as detailed below.

4.2 Acquire leadership permission and support

Firstly, obtaining leadership approval and support was critical to ensure foundational backing for the changes. Upper management and the laboratory manager were briefed on the theories and potential benefits, including enhanced effectiveness and efficiency, more reliable analytical results, reduced experiment

delays, improved laboratory safety, and increased employee morale. The significance of employee involvement was also emphasised, highlighting that successful implementation necessitates active participation from a designated group of employees who would manage these tasks alongside their regular responsibilities. Additionally, the financial considerations were discussed, indicating that 5S and Kaizen do not require significant investments in equipment and supplies. Leadership commitment is crucial not only for the initiation but also for the sustainability of these improvement efforts, as daily engagement from management fosters a culture of continuous learning and innovation, as noted by Bessant (2003).

4.3 Form a Kaizen team

Next, a dedicated Kaizen team was established, consisting of members from various laboratory working groups, including a manager and three analysts. The primary responsibility of this team was to identify and resolve work-related issues, escalating concerns to upper management when necessary. From the beginning, the Kaizen team worked closely with the Quality Assurance (QA) and Human Resources (HR) departments. QA professionals provided insights on quality-oriented procedures, while HR specialists offered advice on behavioural matters. This collaboration aimed to promote a culture of continuous improvement throughout the laboratory. The team also implemented and maintained 5S techniques, which are essential for fostering this improvement culture. Oakland (2014) underscores the significance of regular communication among team members. Meetings were conducted either in the work area or in a designated space to minimise disruptions and encourage open dialogue. These meetings typically addressed various topics, including training sessions, problem identification and analysis, solution recommendations, and updates on 5S implementation. The format and frequency of these meetings were tailored to the specific issues at hand, ensuring focused and effective discussions.

4.4 Provide training sessions

Training sessions were also conducted for all personnel in the analytical laboratory, structured in two distinct parts to comprehensively cover the methodologies of continuous improvement and 5S. In the first session, the concept of Kaizen was introduced, and its historical development, its application in the workplace, and the positive impacts observed in companies that have embraced its philosophy were discussed. Al Smadi (2009) categorised the core principles of Kaizen into two main groups: Continuous Improvement and Respect for People. The former emphasises the importance of forming a long-term vision, fostering innovation, building consensus, and realising personal growth alongside company evolution. The latter focuses on respecting colleagues, customers, and external associates, building mutual trust, enhancing teamwork, and committing to ongoing education and personal development. The second session focused on the 5S system, exploring its origins and the significant benefits of its application,

including the necessity of self-discipline among staff to maintain the changes introduced. During this session, the roles of the Kaizen team members were clearly defined to ensure alignment with the laboratory's new operational strategies. These training and development sessions are pivotal in instilling a culture of continuous improvement and are scheduled to occur regularly. This ongoing educational effort is coordinated by the Kaizen team in collaboration with HR specialists, ensuring that all employees are consistently engaged and the methodologies are effectively integrated into daily operations.

4.5 Conduct current state assessment

Prior to initiating the 5S activities, a current state assessment was performed through direct observation. This assessment identified several issues, including misplaced equipment, a suboptimal layout resulting in excessive travel distances, and inefficiencies in task execution. These findings established a foundation for targeted improvements and created a baseline for measuring the impact of the implemented methodologies.

4.6 Implement 5S activities

The 5S principles were implemented in the laboratory to standardise working procedures and enhance quality effectiveness. Following an assessment of the current state, the "Sort" phase was initiated. The Kaizen team identified unwanted items within the laboratory and marked them with a red label. All items designated with a red tag were collected in a specific area allocated for this purpose. These items included broken equipment parts, obsolete consumables, and equipment belonging to other departments. Additionally, empty cardboard boxes and unnecessary packaging materials were promptly disposed of to optimise the workspace. Chemical reagents, including solids, liquids, bases, and acids, were examined for expiration dates; expired items were similarly red-tagged and removed from the non-expired ones. All employees were notified about the red-tagged items to ensure that any potentially needed items could be retrieved. It was also recognised that certain tools or materials in an analytical laboratory may be required infrequently, potentially less than every six months. Consequently, items in the red tag area would be retained for a duration of nine months to prevent the disposal of essential tools.

During the "Set in Order" phase of implementing 5S in the analytical laboratory, the focus was on systematically organising and labelling items according to their category and frequency of use to improve efficiency and safety. Solid and liquid reagents were organised alphabetically in chemical cabinets; acids and bases were stored in safety cabinets; analytical standards were placed in designated refrigerator areas; glassware was sorted by volume capacity in drawers; and chromatography columns were categorised by type in closets. Additionally, consumables required for experiments were organised on laboratory shelves. Marking tapes and plasticised labels were utilised to define storage areas clearly

and enhance organisation. Different coloured tapes served specific functions: yellow tape outlined the liquid waste disposal area, black and yellow tape designated zones where items should not be placed, and green tape marked common waste bins. This careful organisation and sorting aimed to significantly reduce the time spent searching for equipment and consumables, ultimately improving laboratory safety and operational efficiency.

The "Shine" phase in the 5S methodology emphasises the importance of cleanliness and the proper functioning of equipment within the laboratory. A weekly cleaning schedule was developed and tailored to the laboratory staff, addressing workstations, glassware, and laboratory benches. Acknowledging the vital role of analytical instruments in producing reliable and high-quality results, similar to the influence of production machinery on output quality, this phase incorporates strict maintenance protocols. While most pharmaceutical laboratories utilise external technicians for routine maintenance, the laboratory under study implemented a TPM system, commonly used for production machinery, to improve the reliability and performance of its equipment. Based on the proactive nature of the TPM approach, which aims to identify and resolve issues before they arise, a weekly maintenance schedule was established. Each analyst was assigned responsibility for the maintenance of their respective analytical equipment, following standardised procedures specific to each type of equipment to enhance instrumental efficiency. This focus on regular maintenance and cleanliness not only improves the laboratory's visual conditions but also enhances safety and ensures the effective operation of critical equipment. The success of this method has been demonstrated in other sectors, as noted by Irwansyah, et al. (2019), who reported increased equipment effectiveness in the beverage industry, and Fam, et al. (2018), who observed improved effectiveness in an electronics manufacturing facility after implementing TPM. This phase of the study highlights the significance of diligent maintenance and preventive care in upholding high standards of laboratory operations.

The "Standardise" phase in the analytical laboratory focused on updating and refining existing Standard Operating Procedures (SOPs) by establishing new, detailed laboratory rules and regulations that reflect the changes introduced by 5S-driven activities. Standardising procedures in a dynamic and complex experimental environment poses challenges, as it is difficult to predict future changes in testing methods or materials. This complexity may result in overly detailed procedures that could cause confusion as laboratory practices evolve. To mitigate this issue, Goetsch and Davis (2016) recommend implementing "Kaizen Checklists", which serve as tools for identifying improvement opportunities within the workplace. These checklists encompass all critical elements necessary for the operation of the analytical laboratory, allowing personnel to document observations, ideas, and solutions for problems encountered in their daily activities. A customised checklist was posted on the laboratory noticeboard, encouraging employees to actively contribute by recording issues and potential solutions. This approach promotes employee engagement with departmental

objectives and also aids in automating and streamlining the initial three steps of the 5S activities, ensuring that standardisation contributes positively to laboratory operations.

The "Sustain" phase of the 5S methodology is a vital component of Kaizen, focused on maintaining improvements made in the analytical laboratory. Laboratory staff are responsible for ensuring that changes at their individual workstations become integral to their daily practices. To support the maintenance of these practices, the Kaizen team was authorised to conduct regular laboratory audits. These audits aim to identify any discrepancies from established standards, facilitating prompt corrections to align activities with the principles of 5S and Kaizen. Furthermore, the laboratory has scheduled ongoing education and training sessions on 5S, Kaizen methodologies, and the broader significance of quality. These initiatives are designed to reinforce a culture of continuous improvement and to prevent the decline of laboratory standards over time.

5 CASE STUDY RESULTS

5.1 Quantitative analysis results

The quantitative analysis of deviations in the analytical laboratory involved categorising errors as either due to instrumental malfunctions or employee mistakes, comparing data from the three months prior to and following the implementation of the two examined methodologies. Prior to their introduction, there were six instances of instrument malfunctions and eight analytical errors attributed to human error. After implementation, these figures decreased to four and two, respectively, indicating a significant reduction. This improvement reflects a decrease in total deviations from fourteen to six, thereby demonstrating the effectiveness of the 5S and Kaizen methodologies in reducing both equipment-related and human-related errors and enhancing operational quality in the laboratory environment.

Furthermore, quantitative data were collected regarding the time required by analytical R&D scientists to conduct various experiments, illustrating the effects of implementing 5S and Kaizen methodologies. The times for three different analytical, experimental procedures performed by four employees before and after the implementation demonstrate significant improvements.

For Experiment 1, the pre-implementation times ranged from 55.1 to 65.2 minutes, with an average of 60.5 minutes. Post-implementation, the times decreased to a range of 46.7 to 56.4 minutes, resulting in an average of 51.5 minutes. The detailed times are presented in Table 1.

Table 1 – Experiment 1 conduction times

	Pre implementation (min)	Post implementation (min)	Difference (min)
Analyst 1	65.2	56.4	8.8
Analyst 2	58.9	47.6	11.3
Analyst 3	55.1	46.7	8.4
Analyst 4	62.6	55.3	7.3
Average	*60.5*	*51.5*	*9.0*

In Experiment 2, the initial average was 131.3 minutes, which was reduced to 115.0 minutes after the implementation, as shown in Table 2.

Table 2 – Experiment 2 conduction times

	Pre implementation (min)	Post implementation (min)	Difference (min)
Analyst 1	140.1	123.6	16.5
Analyst 2	129.9	111.7	18.2
Analyst 3	134.2	115.5	18.7
Analyst 4	120.9	109.3	11.6
Average	*131.3*	*115.0*	*16.3*

For Experiment 3, the average time decreased from 191.3 minutes before implementation to 170.7 minutes after implementation, as recorded in Table 3.

Table 3 – Experiment 3 conduction times

	Pre implementation (min)	Post implementation (min)	Difference (min)
Analyst 1	188.4	162.1	26.3
Analyst 2	197.6	177.0	20.6
Analyst 3	179.0	163.3	15.7
Analyst 4	200.2	180.2	20.0
Average	*191.3*	*170.7*	*20.7*

These findings indicate a substantial reduction in the time required to conduct experiments across all three scenarios, reflecting an enhancement in the efficiency of analytical procedures following the introduction of 5S and Kaizen.

A hypothesis test was conducted to assess whether significant differences existed in median experiment conduction times before and after the implementation of continuous improvement methods. The Wilcoxon signed-rank test, a nonparametric method suitable for small samples that do not assume a normal distribution (Berenson, et al., 2013), was employed for the analysis using the SPSS statistics software, involving twelve paired samples. The null hypothesis stated that the median difference between pre- and post-implementation measurements was zero, while the alternative hypothesis proposed a non-zero median difference. The results yielded a p-value of 0.002, which is significantly lower than the 0.05

threshold, leading to the rejection of the null hypothesis. This finding strongly indicates that the differences in median values between the pre- and post-implementation periods are statistically significant, suggesting that implementing 5S and Kaizen methodologies effectively reduced experiment conduction times in the laboratory.

5.2 Qualitative analysis results

This analysis provides insights from laboratory scientists regarding the impact of 5S and Kaizen methodologies on their work routines across seven distinct aspects. Firstly, the organisation of the laboratory workspace was examined. Responses indicated an improvement in perceptions of the organisation post-implementation. Similarly, cleanliness in the laboratory was also perceived to have improved, suggesting better maintenance of the workspace after the methodologies were implemented. The ease of locating drug samples, experimental materials, and equipment—essential for daily operations—showed significant improvement, demonstrating the effectiveness of the new methodologies in organising and labelling these resources.

Additionally, the readiness of analytical instrumentation for use, which is critical for operational efficiency, was perceived to have improved, indicating a reduction in malfunctions and delays. Open communication among laboratory members, important for collaborative efforts, exhibited a slight improvement, potentially enhancing problem-solving and operational efficiency. Employee involvement in identifying work-related issues showed the most substantial improvement, indicating strong engagement with the introduced continuous improvement processes. Finally, the overall work atmosphere and morale in the laboratory were perceived to be better, reflecting a positive shift in the work culture and environment. These changes suggest that the implementation of 5S and Kaizen methodologies enhanced the physical aspects of the laboratory environment and positively influenced work culture and employee engagement.

6 DISCUSSION AND CONCLUSION

This study examined the implementation of two continuous improvement methodologies, 5S and Kaizen, in an analytical R&D pharmaceutical laboratory to assess their effects on experimental processes, the quality of analytical results, employee engagement, and the workspace cultural environment.

The study revealed substantial improvements in the reduction of recorded deviations and errors linked to human factors and instrument malfunctions. The decrease in analytical errors was particularly notable, with human errors declining by 75%, from eight to two errors. This improvement can be primarily attributed to the effective application of the 5S technique, particularly during the "Sort" and "Set in Order" phases. In the "Sort" phase, unnecessary items that had not been used for an extended period and were considered impediments were eliminated. In

the "Set in Order" phase, essential items such as chemical reagents, samples, and analytical microequipment were systematically organised into designated locations. The "Shine" phase focused on maintaining cleanliness, which improved the condition of laboratory glassware and materials, thereby further minimising errors during experimental procedures. Instrument malfunctions also decreased, albeit to a lesser extent, with a 33.3% reduction from six to four incidents. This improvement was largely due to the incorporation of a Kaizen tool (i.e., TPM) during the third phase of 5S. Each laboratory analyst assumed responsibility for the weekly maintenance of an analytical instrument, adhering to standardised cleaning and preventive maintenance protocols. This strategy enhanced the reliability of analytical results by reducing equipment-related errors, which could have serious implications for quality and lead to delays in analytical outcomes, and also cultivated a sense of responsibility and awareness among personnel regarding equipment upkeep. Nishal, et al. (2018) supported this finding in their study, demonstrating that involving personnel in TPM positively influences productivity. Thus, the combined application of 5S and Kaizen methodologies significantly reduced errors in the laboratory's workflow, thereby improving both the accuracy of experimental results and the overall operational efficiency of the laboratory.

Furthermore, the implementation of the methodologies significantly decreased the time required for experiments in the analytical pharmaceutical laboratory. Following the adoption of the 5S technique, notable improvements were observed across various experiments. Specifically, the duration of the first experiment decreased by approximately 14.9%. The second and third experiments also exhibited significant reductions of 12.4% and 10.8%, respectively. The 5S methodology played a crucial role in these enhancements by ensuring that all necessary items for conducting experiments were efficiently organised and readily accessible in designated areas. This organisation included the systematic arrangement of drug samples, analytical standards, chemical reagents, and clean glassware, as well as the proper placement of all essential equipment and tools. The reduction in experimental time improved the operational efficiency of the laboratory and enhanced the quality of analytical results. With less time spent searching for equipment and materials, laboratory personnel can dedicate more time to thorough sample preparation and execution of analyses. Furthermore, the time savings can be utilised for additional research and reading related to the pharmaceutical sector, thereby deepening staff knowledge and expertise, which may lead to advancements in experimental design and execution.

The qualitative investigation conducted before and after the implementation of the 5S and Kaizen methodologies in the laboratory revealed significant improvements in various aspects of laboratory operations and the workplace environment. Participants reported enhanced organisation and cleanliness, decreased time spent searching for equipment, and stabilised machinery performance. These findings indicate that 5S and Kaizen effectively optimised the laboratory's physical layout and operational efficiency.

Furthermore, the study identified notable positive changes in communication, employee engagement in problem-solving, and the overall work atmosphere. Communication among team members, as well as between analysts and managers, improved, reflecting the focus during training sessions on the benefits of enhanced team interactions. This observation aligns with Wickens (1990), who noted that improved communication through Kaizen positively influences corporate performance.

Employee involvement in identifying and resolving work-related issues demonstrated the most significant improvement, indicating a transition from disagreement to consensus regarding their active participation in troubleshooting. This increase is supported by continuous improvement training that emphasises consensus-building and achieving goals beneficial to both the company and individual employee development. Hyland, et al. (2004) highlighted that such engagement enhances performance by promoting development, empowerment, and participation.

Additionally, there was a positive increase in the work atmosphere and employee morale, corroborating findings by Karvounis (2021) and Teshome (2018), who reported similar improvements in employee attitudes and job satisfaction following the implementation of 5S and Kaizen. These methodologies foster a better work environment, higher morale, and increased productivity, thereby reinforcing a strong team spirit.

Top management also recognised the broader impact of these changes, emphasising the importance of initial resource allocation for training and the adaptation to new practices. Despite potential challenges, such as resistance to change from both managers and staff, the existing corporate culture, which was already inclined towards continuous improvement, facilitated the integration of these methodologies. Management's commitment to actively participate in 5S and Kaizen activities has been crucial in cultivating a healthier and more productive workplace environment.

Further research should be conducted over an extended application period to enhance understanding of the impacts of 5S and Kaizen methodologies in pharmaceutical R&D laboratories. This duration will enable laboratory personnel to effectively integrate and understand these continuous improvement methodologies' complexities and long-term advantages. It is anticipated that, over time, refinements and customisations to the five phases of 5S will be developed to address the specific needs and challenges of the laboratory environment. Furthermore, given that Kaizen is a philosophy that adapts with practice, ongoing education and training should be prioritised. This approach will ensure that all team members, particularly those initially resistant, can better comprehend Kaizen's principles. Future studies should incorporate a larger sample size to enhance the validity and reliability of the findings. Including more analytical scientists within the laboratory will help reduce potential biases and provide a more comprehensive dataset, reflecting the methodology's effectiveness across diverse

individuals and teams. Additionally, maintaining a sustained commitment to the 5S and Kaizen culture is essential for validating the relationship between these methodologies and continuous improvements in quality, efficiency, and workplace morale. This ongoing commitment will also support observing gradual changes and the potential cumulative benefits of these continuous improvement strategies within the pharmaceutical R&D context.

ACKNOWLEDGEMENTS

The publication of this paper has been partly supported by the University of Piraeus Research Center.

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Investigation, C.S.B.; Resources, C.S.B.; Data curation, C.S.B.; Original draft preparation, C.S.B., P.T.C., A.I.M., and N.C.; Review and editing, A.I.M. and N.C.; Visualization, C.S.B.; Supervision, P.T.C.; Project administration, A.I.M.; Funding acquisition, P.T.C.

CONFLICTS OF INTEREST

The authors declare no conflict of interest. The funders had no role in the design of the study, in the collection, analyses, or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.