

Design of the Occupational Health and Safety Management System for a Pharmaceutical Products Marketing Company at the Bogotá Headquarters, applying ISO 45001: 2018.

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The high accident rates, occupational diseases, and occupational illnesses have brought significant concerns in the different business activities, therefore over the years, rules have been generated to regulate and control the risks and diseases that employees may be subject to during work activities. Thus, the ILO (International Labor Organization) has provided provisions and regulations on OHS issues, and Colombia has adhered to them as a member state. In this respect, many companies around the country are committed to ensuring employees' health and providing safety to them during the development of their activities. A clear example of the above is a company whose activity is the commercialization of pharmaceutical and medicinal products, cosmetics, and toiletries, which has currently positioned itself as one of the leaders in this sector. This company has been in business for more than 20 years and has more than 960 points of sale throughout the country. Thus, after an extensive review of the company's guidelines and directives, it became evident that there are shortcomings in the lack of an OHSMS. Although some of the country's OHS regulations are applied, the need to apply a standard like ISO 45001 is highlighted. The application of ISO 45001 helps companies minimize significant risks that cannot be overlooked and improve quality standards, giving employers and employees more confidence. This work focuses on designing the management system for occupational safety and health of a company marketing pharmaceutical products in one of its offices located in Bogota. For this purpose, the requirements of the international standard ISO 45001:2018 are considered, and its implementation is intended to make employees feel at ease and safer when working. It should be noted that, for the company, the design of the Occupational Health and Safety Management System (OHSMS) will facilitate risk management and reduce the likelihood of occupational illnesses and accidents to which employees may be exposed. Additionally, it is expected that with the system's design, the company can be directed towards increasing the performance and continuous improvement of the organization, and it may involve having an advantage over companies that do not yet comply with this standard.

1. Introduction

During the ILO's centenary framework, the ILO's Centenary Declaration for the Future of Work was issued, advocating for a future of work and being people-centered. This task is particularly urgent because the COVID 19 pandemic crisis has also highlighted the situation of poverty and inequality in the world. While this already existed, social justice and dignified work must be achieved to attain universal and lasting peace. The ILO declaration sets out a roadmap for creating a safer, inclusive, and just world with dignified work for all (World Health Organisation and International Labour Organisation, 2021). In addition, Goal 8 of the Sustainable Development Goals and targets of the UN 2030 Agenda mentions, among other things, that dignified work must be achieved for all women and men, including youth and people with disabilities. Equal pay for work of equal value must also be achieved, labor rights should be protected, and a safe and secure working environment promoted for all workers, including migrant workers, particularly migrant women and those in precarious employment (United Nations, 2021). It highlights the importance of implementing occupational health and safety (OHS) management systems in companies to prevent injuries and illnesses among workers.

Providing safe and healthy workplaces (ISO, 2018). ISO 45001 is the first international standard that determines the requirements for implementing an occupational health and safety system. The objective is to provide safe and healthy working conditions, prevent injuries and deterioration of health, and improve occupational safety and health performance, involving workers and visitors, and contractors of the organization (Rojas, 2020).

About 2 million people die each year from work-related causes, and more than 300 million accidents occur at work, many of which could have been avoided (Liukkunen, 2021). Creating favorable working conditions and labor relations is essential for optimizing the work process and positive economic effect. It also leads to reduced losses, increased productivity, efficiency, and quality of work, which means greater prosperity for the company and society (Nagyova, 2017). Although, regularly many companies, regardless of their corporate purpose, present accidents, and professional risks due to daily work, which turns out to be an intolerable situation since it is necessary that they fully have a duly regulated OHSMS.

In Colombia, countless companies within their areas comply with the documentation regulations, such as laws, decrees, and resolutions established by the country regarding OHS (Ospino and Galán, 2019). However, this is not enough to mitigate the number of occupational risks and accidents daily in the workplace. The company's case addressed during this study, which has a trajectory of more than 20 years and whose activity is the commercialization of pharmaceutical and medicinal products, cosmetics, and toiletries. That currently has more than 960 points distributed throughout the country, and the previously mentioned problem is not unrelated. Indeed, once an extensive review of the company's directives and guidelines was carried out, it was shown that it has shortcomings related to the lack of an Occupational Health and Safety Management System (OHSMS). Although some regulations that the country has in OSH are applied, applying a standard such as ISO 45001 is highlighted.

For the pharmaceutical marketing company under study, the Occupational Health and Safety Management System (OHSMS) design will facilitate risk management and identify opportunities to reduce the likelihood of occupational illnesses and accidents to which employees may be exposed. It is expected to be established and implemented to increase its performance and continuous improvement, thus, having an advantage over companies that have not yet implemented this standard. In addition, implementing a successful OHS is related to the maturity of an organization and the number of processes (Castiblanco et al., 2020). Social responsibility is demonstrated by the company when providing security to its workers. The development of this OHSMS design under the requirements of this international standard covers: the diagnosis of OHS in the company to the verification of the legal requirements applicable to Colombian organizations and the continuous improvement established in the standard.

2. Methodology

The methodology used for the design of the OHS is based on the document's provisions marked as Annex SL (Proposals for Management System Standards) issued by ISO in 2012. The document mentions that all international standards must have a uniform HLS framework (High-Level Structure) based on the Plan - Do - Check - Act (PDCA) methodology (ISO, 2015). In the case of ISO 45001, it is applied as follows:

Plan: establish the objectives, programs, and processes necessary to achieve the best results, based on the occupational health and safety policy, as well as identify and assess occupational health and safety (OHS) risks, the opportunities for OHS and other risks, and other opportunities,

Do: Implement all processes as planned.

Verify: monitor and measure the activities and processes according to the safety policy and occupational health objectives, in addition to reporting all the results obtained.

Act: the necessary actions must be carried out to comply with continuous improvement according to the performance of the occupational health and safety management system to achieve the expected results (ISO, 2018).

Figure 1 shows the proposed diagram when the chapters of the ISO 45001 standard are included in the Plan - Do - Check - Act (PDCA) methodology, which was the guide for the achievement of this work.

The risk assessment is based on the risk matrix, considering the parameters of probability (L) and severity (S), where the level of risk and intervention (RL) is determined by the product of the two parameters evaluated ($RL = L \times S$). Table 1 shows the risk assessment matrix, considering the probability levels and severity levels, where 100 is the highest value, or cause of death for severity, probability in four levels, and the risk level with a maximum value of 4000, as shown in Table 1, where a description is given for the severity levels. This matrix is taken from ICONTEC (2012).

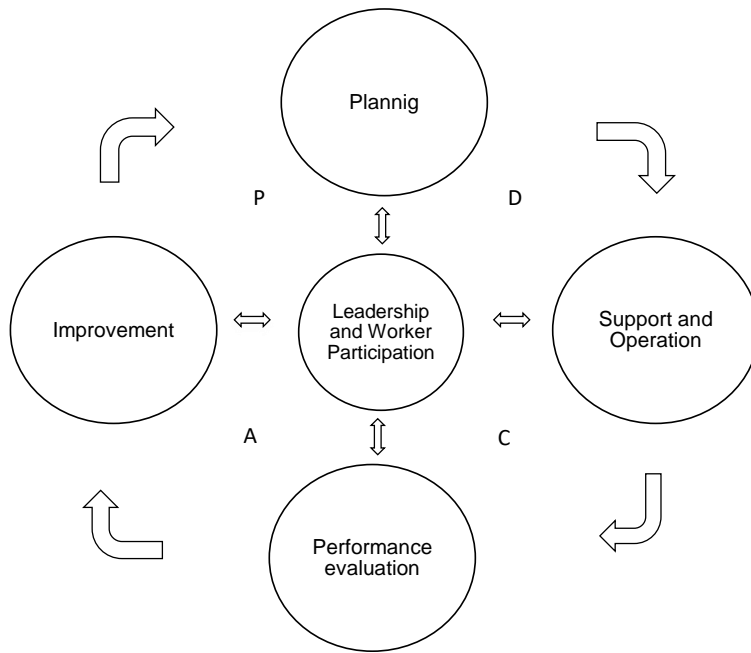


Figure 1: OHS management system model based on ISO 45001 (adapted ISO, 2018)

Table 1: Risk matrix

Severity(S)		Likelihood (L)				Risk Level (RL)	
Level	Description	40-24	20-10	8-6	4-2	Level	Description
100	Death	I 4000-2400	I 2000-1200	I 800-600	II 400-200	I 4 000 - 600	Critical situation. Suspend activities until the risk is under control. Urgent intervention.
60	Irreparable serious injuries or illnesses (Partial permanent disability or invalidity)	I 2400-1440	I 1200-600	II 480-360	II 240 - III 120	II 500 - 150	Correct and take control measures immediately. Nevertheless, suspend activities if the risk level is above or equal to 360.
25.	Injuries or illnesses with temporary incapacity to work (ILT)	I 1000-600	II 500-250	II 200-150	III 100-50	III 120 - 40	Improve if possible. It would be appropriate to justify the intervention and its profitability.
10	Injuries or illnesses that do not require disability.	II 400-240	II 200 - III 100	III 80-60	III 40 - VI 20	IV 20	Maintain existing control measures but should be considered solutions or improvements and regular checks should be made to ensure that the risk is still acceptable.

3. Analysis and results

The area in which the company operates is wholesale and retail marketing of pharmaceutical and medicinal products, cosmetics, and toiletries in specialized establishments. It is essential to mention that the company has 960 points distributed in 100 cities around the country, and it has four work centers in which all the personnel are divided. These are administrative services (188 people), points of sale (1260 people), distribution center (92 people), and the fleet of couriers (321 people).

3.1 Analysis of the current situation of the company

The company has an Occupational Health and Safety Management System governed by the country's regulations. The regulation by which the company's OHSMS is followed focuses on risk (but mentions the risk plan coverage for workers as a fundamental component). Its purpose is to protect workers' safety and health; also, the importance of its national compliance is highlighted to a greater extent (Lasprila et al., 2019). However, the company plans to reach the international labor market. For this, it needs to have an updated OHSMS based on international standards, allowing it to carry out its activities in different countries. For this, verification was made using the checklist for the ISO 45001 standard. According to the checklist of 496 requirements, it was obtained that the compliance is equivalent to 71 %, in Table 2 can be seen.

Table 2: Indicators of compliance according to the checklist

Indicator	Number of Requirements	Percentage Requirements
Complies	423	71 %
Non-compliant	73	29 %
Total	496	100 %

3.2 Leadership and worker participation

Supported by the findings and to comply with the standard, the company must be invited to take leadership from senior management and commit to:

- Inclusion of workers to participate proactively in the Joint Health and Safety at Work Committee (JHSC) and the Work-Life Committee.
- Ensure that all the necessary resources are in place to implement the OHSMS.
- The company's management assumes responsibility for the leadership of the OHSMS.
- Be committed to sustaining the Occupational Health and Safety Management System and its continuous improvement.
- Ensure an induction, training, and coaching program according to specific OHS needs.
- To have suitable personnel available for the proper implementation of the OHSMS.
- Encourage all workers, visitors, and suppliers to take responsibility for safe practices and comply with the company's standards for individual and collective protection.
- Any member of the company, visitor, or service provider must notify promptly of all situations that may generate contingencies and consequences that impact business continuity. The organization is committed to maintaining the available channels of communication and participation.
- Create and disseminate to the staff a manual of functions and organizational charts of the positions in the company.

The following sections provide the application of the PDCA concept during the design of the system for the company.

3.3 Plan

In this section, the actions aimed at eliminating or correcting the risks and finding the opportunities for improvement were addressed, the objectives and activities to achieve it were also raised. The identification of hazards and the evaluation of risks and opportunities is achieved from developing the risk matrix. The matrix was prepared considering the legal requirements for Colombia and the ISO 45001 standard. As a result of the evaluation, six critical points are located, two in the points of sale, two in administrative services, one in the distribution center, and one in couriers. One of the risks is due to inadequate storage of material and the other due to occupational stress associated with the demanding work pace in the administrative area; each of these risks reports a value of 700, according to the matrix presented in Table 1, which would correspond to high risk. Like actions to mitigate these risks are suggested: installing racks for the storage and organization of the material

and implementing standards to store materials (according to their nature, size, and shape). In addition, workshops on work stress management, customer service, and group relationships. Likewise, the promotion and incentives for practicing some sport and recreational activities. In the administrative staff, two risks were identified, one due to screens and surfaces that reflect light causing visual fatigue headaches. The second was repetitive movements that cause muscle spasms and repetitive movements. According to the weighting in the matrix from Table 1, the value found was 700 and 1000, respectively, which would correspond to high risk. It is proposed, training in ergonomic concepts, active breaks to activate and relax some muscles, improve postures, and change chairs, adding footrests. On the other hand, a mechanical risk was identified in the distribution center due to improper use of tools and handling of objects in an unsafe way, causing blows, falls, bruises, and severe traumas. According to the risk matrix, which is reported as high risk, given that the assessment is 700, for this reason, it is recommended to create workshops on handling hand tools, induction on their use, maintenance, and safe handling of heavy objects. Additionally, couriers have a high risk of getting run over, blows, and collisions with and against vehicles due to the nature of their work, which can cause injuries of varying severity. This risk was weighted in the matrix with a value of 1000. It is proposed to mitigate this risk by training preventive management, traffic risks on the roads, compliance with current circulation regulations, and self-care.

3.4 Do

The organizational communication manual was created with internal and external communication procedures, and areas involved. This manual will contribute to the agile circulation of information as an input for timely decision-making and achieving a consistent and fluid approach and dialogue with its internal and external clients. It is crucial to indicate that the communications area will manage the information and basic strategies of the company to specify and convey the key objectives to be met. On the other hand, procedures were established for the competence, awareness, and training of personnel who perform some function for the company, and that may cause impacts on Occupational Health and Safety. Likewise, the registration and change control documents were defined, where the methodology to identify and describe the processes and procedures of the company is established and specified in detail; this ensures that the documents handled in the company are prepared, codified, reviewed, approved, published, distributed, and managed by the company's specifications. As mentioned at the beginning, the company follows the country's regulations and guidelines. The regulations contemplate allocating financial, technical, human, and physical resources for compliance with prevention and control measures in terms of OHS. However, within the financial findings, it was detected that it is partially executed despite having an item assigned for risk management (which includes emergency care and drills) (64% of the assigned value). This aspect is emphasized in updating competition procedures, awareness, and training. It is worth mentioning that the information concerning the financial resources is not presented in this section since it is the company's sensitive information. Likewise, to comply with the operation control, the operational control, monitoring, and improvement procedures were created to prevent and control possible risks and dangers in the company. The procedure is accompanied by the risk manual that provides clear guidance for its application at the organizational level and promotes effective decision-making regarding the risks that tend to affect the achievement of the company's mission and objectives, with a view to proper monitoring and continuous improvement. This procedure includes that it be extended to suppliers and contractors. In the same way, for the preparation and response to emergencies, the prevention, preparation, and emergency response plan was established for the administrative headquarters and points of sale were developed. Within them, the existing risks of the different dependencies are defined, locating the direction and the actions that must be carried out to eliminate or mitigate them, and thus avoid the negative consequences these can generate for the collaborators, equipment, facilities, and other assets of the company. For its implementation, this document contains the following components: The risk analysis of the points of sale and administrative headquarters, where the vulnerability to the identified threats is assessed, triggering an emergency that warrants activating the contingency plan; the administrative organization of the plan, where the human and physical resources available to attend an emergency in this office are defined; the contingency plans for each threat indicate the protocols to follow in each event before, during, and after its occurrence. This point is the essence of the Emergency Prevention, Preparedness, and Response Plan. Finally, the activities necessary to develop an Evacuation Plan are related, showing the procedures and logistical requirements necessary to carry it out, either in a drill or in a real event.

3.5 Check

For the fulfillment of this stage, together with the control, monitoring, and operational improvement procedure, the internal audit procedure is created to define whether the system is established, maintained, and implemented according to the criteria established by the company. Additionally, this stage is supported by the matrix of legal requirements. According to what the country's regulations have defined it, the documentary

approximations of the OHSMS that the company has (according to what the country's regulations have defined it) presents compliance of 98%. The procedure for review by the company's top management is created, which includes: Annual work plan, Resources for the occupational health and safety management system, Changes to the occupational health and safety management system, Occupational health and safety policy and objectives, Results of occupational health and safety management system indicators, Effectiveness of prevention and control measures. This procedure is based on the quality management system's measurement, analysis, monitoring, review, and improvement. Additionally, it is emphasized that this procedure will be carried out annually.

3.6 Act

Within this cycle stage, the system is also supported by the operational control, monitoring, and improvement procedure (previously created). The occupational accident investigation instructions are developed (which includes the description of the facts, the losses generated by a human, material, environmental or equipment type, the background and observations regarding the accident, the causes, the prevention measures to draw the necessary correctives). Likewise, the incidents, non-conformities, and corrective actions procedure is carried out. It is intended to eliminate the causes of non-conformities to optimize the performance of the processes and take improvement actions. For this procedure, the monthly periodicity is defined since the different action plans will be generated based on the different security inspections for the validation of compliance and implementation of the system. In this way, it complies with the provisions of ISO 45001. It conforms to the PDCA cycle, thus ensuring that the creation of the route can meet the objectives set within the organization to achieve them and the different actions for measuring progress towards their achievement.

4. Conclusions

According to the initial diagnosis, the organization has a management system that must be updated and adjusted to comply with the international standard ISO 45001. The procedures and documentary supports are created for each numeral of the ISO 45001 standard framed in the PHVA cycle, which will serve as a valuable tool for implementing the occupational health and safety management system. The company shall ensure the continuous improvement of the OHSMS through continuous monitoring to comply with the minimum standards established by ISO 45001 and the regulations in force in the country. A matrix was defined to identify hazards, evaluate, assess risks, establish controls. This matrix will impact workers, contractors, and subcontractors, and it also contributes to the improvement of the working environment. Finally, it is essential to highlight that for the success of the OHSMS. It must be aligned with the legal regulations in force and the availability of the human, physical and financial resources necessary for its management.

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