

Design of a quality management system for a pharmaceutical company

Diseño de un sistema de gestión de la calidad para una empresa farmacéutica

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Abstract

This project was carried out in a company that sells and distributes medicines, it is striving to improve the quality of the service, which is why it is aiming to design the quality management system based on the processes approach and compliance with ISO 9001:2015 regulatory requirements. To fulfill the objective, the following activities were carried out: processes mapping, context analysis, risk identification, stakeholder mapping, establishment of quality policy and objectives, and development of a control plan. The results indicate the following key processes: purchases, inventories and sales, strategic prospecting, supply and support; management of human resources, technology and finance. Most influential stakeholders; in the client category, the Instituto Mexicano del Seguro Social, private hospitals and laboratories; in the provider category, PISA laboratory and independent drug distributors, in addition, the scope of the management system, policy and quality objectives were established, as well as a control plan for the system's risk management. Critical risks include not having developed mechanisms for electronic commerce and the lack of a Quality Management System. The countermeasures consider creating and designing an e-commerce store and implementing the Quality management system.

Process Approach, Quality, ISO9001

Resumen

Este proyecto se realizó en una empresa que vende y distribuye medicamentos, tiene interés en mejorar la calidad en el servicio, razón por la cual el objetivo es diseñar el sistema de gestión de calidad basado en el enfoque a procesos y cumplimiento de requisitos normativos ISO 9001:2015. Para dar cumplimiento al objetivo se realizaron las siguientes actividades: mapeo de procesos, análisis del contexto, identificación de riesgos, mapeo de partes interesadas, establecimiento de política y objetivos de calidad y desarrollo de plan de control. Los resultados identificaron procesos claves: compras, inventarios y ventas, estratégicos prospectación y proveeduría y de apoyo gestión de recurso humano, tecnología y finanzas. Las partes interesadas con mayor influencia; en categoría clientes el Instituto Mexicano del Seguro Social, hospitales particulares y laboratorios, categoría proveedores; laboratorio PISA y distribuidores de medicamentos independientes, adicionalmente se estableció el alcance del sistema de gestión, política y objetivos de calidad, así como un plan de control para la gestión de riesgos del sistema. Los riesgos críticos incluyen el no tener desarrollados mecanismos para comercio electrónico y falta de un Sistema de Gestión de Calidad. Las contramedidas consideran, crear y diseñar una tienda e-commerce e implementar el Sistema de Gestión de Calidad.

Process Approach, Quality, ISO 9001

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Introduction

The pharmaceutical industry for human use is one of the most innovative industries due to the appearance of new viruses and diseases in general, for which it requires constant updating to adapt to the health needs of humanity; since a healthy, creative and innovative pharmaceutical industry leads to a better quality of life for society (Castro, 2018).

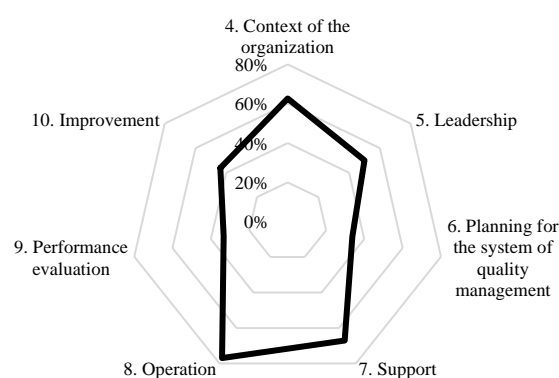
One of the events that has revolutionized this sector is the declaration of a global pandemic in 2020 due to the appearance of a new disease called COVID-19 caused by a new virus called SARS-CoV-2; because of this, pharmacists around the world continue to play a very important role in the fight against this disease (Song, Hu, Zheng, Yang, & Zhao, 2021). (Jordan, Guiu-Segura, Sousa-Pinto, & Wang, 2021) They establish that the global health crisis derived from COVID-19 is pushing all the health systems to the limit, including the richest countries and those with the best health statistics.

In addition, this crisis has also shown that pharmacists, researchers, and pharmacies are a fundamental and essential part of any health system in any country. Therefore, the pharmaceutical sector has also been called upon to ensure the supply of health products and medicines and, where appropriate, to manage their shortages to deal with this disease.

In Mexico, the pharmacy business has evolved, currently, in addition to medicines, you can find a wide variety of nutritional products, personal hygiene or even a medical office. Due to the maturity of the market for health products and the prevailing regulatory environment in this country, the Federal Commission for Protection against Sanitary Risks (COFEPRIS) has issued various regulatory provisions, all for the benefit of the Mexican population, although on the other hand it requires greater maturity for businesses in the field and all those involved, such as suppliers, distributors, and even those who manufacture products and offer services (Lara-Aké, 2020).

Derived from the new challenges of the pharmaceutical industry to ensure the supply of medicines for the health sector and looking to improve the sales services and be more competitive, the company for this study is approached; located in Ciudad Obregón, Sonora, the company aims to provide medicines to the health professionals, its main client is the Mexican Institute of Social Security (IMSS) both in Ciudad Obregón and Guaymas, as well as Navojoa, but they also provide medicines to private clinics, private offices and even to pharmacy.

To determine the current status in relation to the compliance of a model of a quality management system, a self-diagnosis evaluation was carried out in close association with the employer, for which a questionnaire was used with a series of questions based on the requirements of the clauses 4 to 10 from the ISO 9001:2015 Standard, in this regard, the company is evaluated in the most realistic way in order to detect the gaps that exist in compliance with said evaluation standard, the overall results are found in the graph 1.



Graph 1 General results of the evaluation of the clauses of the ISO 9001:2015 Standard

Source: Own Elaboration

Derived from this self-assessment, it was detected in the company under study that there is a major area of opportunity in the clauses 6 (planning for the quality management system) and 9 (performance evaluation), despite the fact that the company has established its organizational philosophy, the gap is found in some of the requirements of the standard in which it requests documented information regarding the scope and object of the quality management system.

The quality policy and the quality objectives which represent a substantial part for the design of the system, in addition that it does not have indicators to measure the level of service that customers perceive, nor does it have the knowledge of the impact generated by its services and products on customer satisfaction.

Objective

Design the quality management system for the company through context analysis, processes mapping, SIPOC diagram of the key process, mapping of interested parties and the production of documented information to lay the foundations for compliance with ISO 9001:2015.

2. Theoretical framework

For Deming, quality consists of transforming the needs and expectations of the client in a quantifiable and measurable facet, thus enabling a way to design and develop products and/or services for which the client will be willing to pay, thus achieving their full satisfaction; therefore, derived from this conception, we learn that quality can only be measured from the customer's perspective (Hernández, Barrios, & Martínez, 2018). On the other hand, (Organismo Internacional para la Estandarización [ISO], 2015) defines quality as the degree to which a set of inherent characteristics of an object meets the requirements. Given these two definitions, the customer is the main focus to consider in the design of a Quality Management System.

Quality is a topic that has become relevant in recent times, every day one is in contact with products or services, which are constantly changing, competing with each other and displaying particularities such as better prices, or better ingredients. Taking into consideration that companies are striving to be competitive in order to stay in the market (Novillo, Parra, Lopez, & Ramón, 2017).

Nowadays, customers can choose due to the wide range of products that exist, and in most cases, they do so based on perceived quality. In particular, quality affects a company in four ways:

1. Costs and market share: improvements in quality lead to greater market share and considerable cost savings due to fewer failures, rework, and return guarantees.
2. Prestige of the Organization: the perception of quality will arise from the experiences that customers have about the company's new products and also from the practices of employees and relationships with suppliers.
3. Product Liability: Organizations that design and manufacture defective products or services may be held liable for damages or injuries resulting from the use of their products. This leads to large legal expenses, and negative publicity that does not prevent the failure of the organization.
4. International implications: in a globalized world, quality is considered an international issue. Both for a company and for a country. In effective competition within the global economy, products must meet quality and price expectations. (Carro & González, 2012).

Considering the above (Sánchez - Tembleque, 2016) it is deemed that, in the long term, improving the quality of products can reduce their real cost. In addition, using better trained and competent personnel enhances the flexibility and adaptability of companies, this allows prices to be reduced and sales to be increased.

The quality of customer service is one of the essential points that must be met within companies; Regardless of their size, their structure and the nature of their operations, they must be able to demonstrate their ability to perform in their area, given that the first image customers perceive helps maintain their preference, and if a customer becomes upset, they can become a threat (Solórzano & Aceves, 2013). (Haro, y otros, 2018) They conceptualize a quality management system as the way in which the organization carries out business management associated with quality. In general terms, it consists of the organizational structure together with the documented information of the processes and resources that are used to achieve its quality objectives and meet the established requirements of the clients.

On the other hand, (Rojas, 2016) defines it as a set of interrelated elements of a company or organization that manages its quality in an orderly manner, in the search for the total satisfaction of its clients. Likewise, quality management systems are part of the tools required for the organization to achieve quality goals and objectives, offering customers confidence and security in the products and/or services they receive.

A quality management system must be designed following the processes approach, which includes the establishment of the organization's processes to operate as an integrated and complete system, it also integrates measures for the fulfillment of objectives, defines activities and interrelated verifications to deliver the intended results, it documents planning and controls as needed in the context of the organization. In addition, it includes risk-based thinking and the application of the PDCA cycle (Plan, Do, Check and Act) (Organismo Internacional para la Estandarización, 2015).

The implementation of an ISO 9001-2015 management system brings efficient results, presenting improvements in the quality of services due to the flow of communication channels with clients, as well as the proposal and execution of a training program for its collaborators and the self-inspection of senior management, the role of the latter in the design of the implementation strategy of the ISO 9001-2015 Standard, is of the utmost importance, considering that they will be the main promoters of compliance with the requirements of the clients and their stakeholders seeking constant involvement and commitment. (Ancasi & Romero, 2018).

(González, Batista, & González Fernández, 2020) present a model for the design of a quality management system (QMS) which is based on the seven principles of quality management according to the ISO 9001: 2015 standards. On the other hand, one of the most well-known and used models at an international level is the one proposed by the ISO Standard, which manages quality by also applying the seven principles and a continuous improvement approach through the Deming cycle Plan, Do, Check and Act (PDCA) that can be applied to all processes and to the quality management system as a whole (Organismo Internacional para la Estandarización [ISO], 2015).

3. Method

Object of study

The object of study of this research project is a medicine distribution company located in Ciudad Obregón, Sonora.

Materials

- Structured interviews with senior management.
- Self-assessment questionnaire for ISO 9001:2015.
- Office package.

Procedure

In order to establish the procedure, the requirements established with respect to the generation of documented information of the ISO 9001: 2015 Standard were taken as a model, developing the following steps:

1. Develop the map of processes.
2. Develop the SIPOC diagram (Supplier-Inputs-Process-Outputs-Customers) of the key process.
3. Carry out the analysis of the context of the company under study.
4. Map out the interested parties.
5. Establish the object and scope of the Management System, Policy, Quality Objectives.
6. Develop control plan.

4. Results

The following diagram (figure 1) shows the processes map that was prepared with the support of the employer in which there are 2 strategic processes that contribute in the political part, goals, quality objectives. The operational processes in which the product goes through a series of steps until it reaches the customer's hands, such as the purchasing, inventory and sales processes, as well as the support processes (human resource management, technology management and finance) which support the other processes.



Figure 1 Processes Map
Source: Own Elaboration

Through unstructured interviews, talks and virtual meetings with the entrepreneur, the SIPOC diagram of the first level was developed, in which the main steps of the key sales processes were established, their inputs, their suppliers were identified, as well as its outputs and its customers, as can be seen in Figure 2 below.

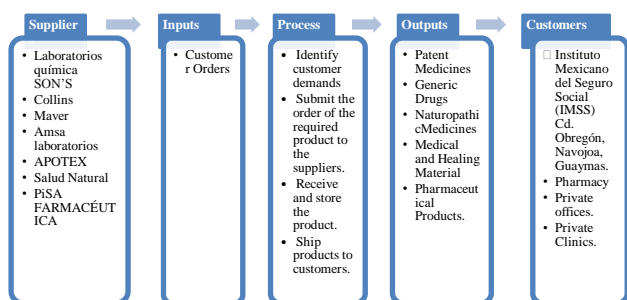


Figure 2 SIPOC Diagram of the key process
Source: Own Elaboration

A context analysis was carried out using the PESTEL technique, where the risks and opportunities that can affect the different factors (political, economic, social, technological, environmental or ecological and legal) were identified.

In addition, the Internal Factors Evaluation Matrix (MEFI) tool was implemented, which was carried out on the company under study through an internal audit to identify both the strengths and weaknesses that exist in all areas of the business. Obtaining strategies that can contribute to solving the risks that the company has, which are presented in table 1.

Strategy	Address Risk
Have an easily accessible website and an online store with product availability	Increase in digital sales
Offer discounts and promotions	Decline in demand
Conduct satisfaction surveys, improve after-sales	Companies with low prices
	Competitive Monitoring

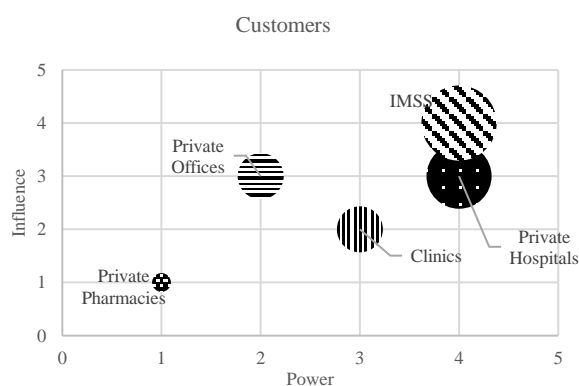
Table 1 Strategies to address risks
Source: Own Elaboration

With the support of the employer and unstructured interviews, the stakeholders that have the greatest influence on the organization were identified, which in addition to identifying them, established their requirements and their level of importance for the organization (see table 2).

Interested party	Requirements	Importance level
Private hospitals and pharmacies	<ul style="list-style-type: none"> Delivery time (same day) Product range specific to the activity Anesthetics Antibiotics Oncological Blood products Healing material Price 	Very high
Clinics	<ul style="list-style-type: none"> Delivery time Price Product range specific to the activity Anesthetics Antibiotics Oncological Blood products Healing material Products related to the activity Maternity Cardiological Specialty products by brand 	
Office doctors	<ul style="list-style-type: none"> Specialty products by doctor's field Surgeon Dermatologist Internists Ophthalmologists Cardiologists Delivery time from 1 to 2 days 	

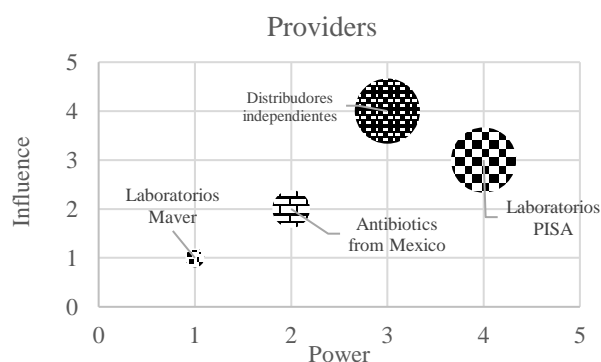
Table 2 Stakeholders in the organization
Source: Own Elaboration

A specific mapping of the interested party clients was carried out, where the influence and power were evaluated, this is with the purpose of being able to appreciate the importance that each one of them represents within the organization and to be able to manage it efficiently (see graph 2), where Hospitals represent a greater importance and private pharmacies a lesser importance despite having the same established requirements, however, Hospitals represent the customer who buys in greater volume.



Graph 2 Mapping of the interested party Clients
Source: Own Elaboration

Additionally, a specific mapping of the supplier's interested party was carried out, where the supplier Laboratorio Pisa and independent Distributors represent a greater importance and Maver Laboratories a lesser importance despite the fact that they have the same established requirements (see graph 3).



Graph 3 Mapping of the interested party Suppliers
Source: Own Elaboration

For the establishment of the Object and Scope of the company's quality management system, the results of the previously prepared context analysis were considered, as well as the requirements of the interested parties, being established as follows:

The scope of this management system covers the purchasing, inventory and sales processes of the pharmaceutical distribution company, whose distribution includes the local region of Ciudad Obregón Sonora, as well as the central and southern regions of the State of Sonora. The organization excludes compliance with requirement 8.3 of the ISO 9001:2015 standard, this is because it does not carry out any design and development of any new product, and the product requirements are regulated in accordance with the technical specifications and established contractual requirements by the customer and the quality of the product.

Subsequently, in order to establish the quality policy, it was deemed appropriate for the context analysis previously prepared, looking to establish quality objectives as well as commitments with respect to the fulfillment of requirements and continuous improvement, being established as follows: the quality policy for the company, its highest priority is to offer a quality service complying with the established standards, with total satisfaction and commitment to the client.

Quality goes hand in hand in each of the daily aspects within the organization, implementing a continuous improvement approach that is promoted in each of the collaborators, from the administrative part to the final delivery of the product to the client. The main commitments are:

- Committed to quality towards customers and suppliers
- A product delivery service in a timely manner
- Have the products complying with quality standards.

Another piece of documented information requested by the ISO 9001:2015 Standard is the quality objectives. For the development of said information, it was ensured that they were consistent with the quality policy, which establishes three quality objectives listed below:

- Expand the client portfolio: Create a plan to approach new customers, offering a variety of products and even expanding the logistics system to reach more cities.
- Implementation of a quality management system: Achieve a certification in the ISO 9001:2015 standard, complying with the requirements with the aim of standardizing quality in the organization, optimizing processes, improving security for customers in the medium and long term.
- Increase customer satisfaction: Carry out customer satisfaction evaluation either by phone calls or through the online store page, offering small surveys to customers to be able to evaluate the service that is being offered.

After determining the risks in the context of the organization, we evaluated them and the level of risk they represented was determined; some actions were proposed to counteract them. In the external technological factor, an extreme level risk was found. There is a lack of new technologies to purchase products in a more effective way, therefore, it was proposed to design an e-commerce store with immediate attention; another risk found as extreme is the lack of a quality management system found in the internal factor of the organization, for this it was proposed to implement the quality management system ISO-9001-2015.

Additionally, three high level risks were detected; inadequate staff process, the product does not arrive within the established delivery time to the client, and clients who go to the competition; to mitigate these risks the following actions were proposed: Have a person in charge of evaluating candidates for different areas, Request support from an external delivery service and offer promotions, discount system to customers through the online store respectively without immediate attention but with high priority.

Conclusion

The objective set at the beginning of the project was met, given that each of the products proposed in the procedure of this project were carried out, from internal and external analysis (context of the organization), strategy design, process mapping, mapping of interested parties and the generation of documented information required by ISO 9001:2015 and a control plan. It was evidenced that the key processes (sales, purchases, inventories) are essential for the fulfillment of the company's objectives, and therefore require records and documentation. However, achieving Total Quality begins with the development of the quality management system.

With the complete development of the quality management system, the company is expected to improve in different aspects to achieve total customer satisfaction and also improve effectiveness and efficiency during its management in order to position itself as one of the most competitive drug marketing companies of the region.

Through this project it is reaffirmed that (Ancasi & Romero, 2018) just as when designing the quality management system, the leader or senior management plays an important role since they are the most interested in achieving the results foreseen by the system, in addition to the fact that in the version of the ISO 9001:2015 Standard, Leadership appears right in the center of the model with bidirectional arrows to all the other modules of the quality model, which gives it greater responsibility for being the one who must provide the necessary resources to perform the functions and operations of the whole system.

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