

Improvement proposal continues developing the EFQM and Hoshin Kanri models in the pharmaceutical industry

Propuesta de mejora continúa desarrollando los modelos EFQM y Hoshin Kanri en la industria farmacéutica

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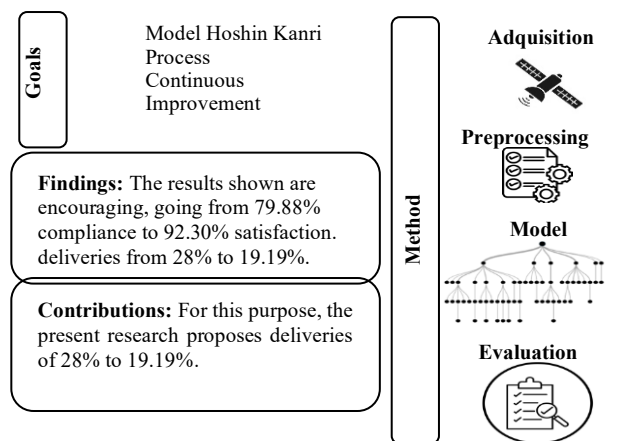


Abstract

This research proposes the incorporation of the Hoshin Kanri process and the EFQM model as an improvement strategy in the pharmaceutical industry. Both methodologies will provide a comprehensive approach, which is a constant in the process of making boxes of medicines for this industry, one of the elements of evaluation is the absence of strategic planning, since it is an international problem, for this purpose the present research proposes both methodologies to address the problem of returns and delays in deliveries, The results shown are encouraging, going from 79.88% compliance to 92.30% satisfaction, and steadily reducing the rate of delays in deliveries from 28% to 19.19%. By implementing both methodologies, Through the Cycle [PDCA], feedback actions will be promoted with a systemic and strategic approach promoting continuous improvement in the organization.

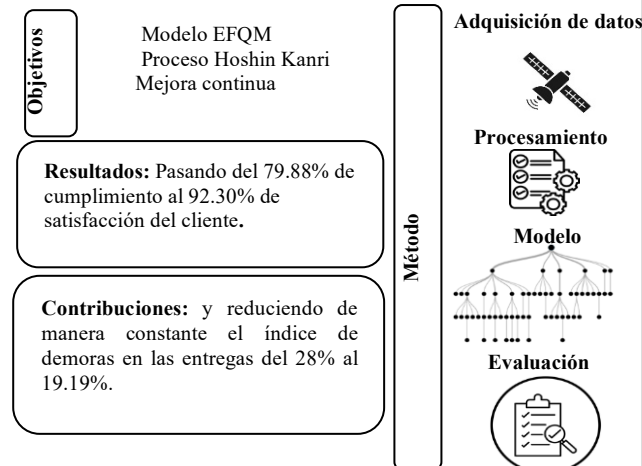
Resumen

La presente investigación propone la incorporación del proceso Hoshin Kanri y el modelo EFQM como estrategia de mejora en la industria farmacéutica. Ambas metodologías proporcionarán un enfoque integral, el cual es una constante en el proceso de elaboración de cajas de medicamentos para dicha industria, uno de los elementos de evaluación es la ausencia de la planificación estratégica, dado que es un problema internacional, para tal efecto la presente investigación propone ambas metodologías aborden el problema sobre devoluciones y demoras en las entregas, los resultados mostrados son alentadores, pasando del 79.88% de cumplimiento al 92.30% de satisfacción, y reduciendo de manera constante el índice de demoras en las entregas del 28% al 19.19%. Al implementar ambas metodologías, A través del ciclo [PDCA], se impulsarán acciones de retroalimentación con un enfoque sistémico y estratégico impulsando la mejora continua en la organización.



EFQM Model, Hoshin Kanri Porcess, Continuous improvement

Area: Development of strategic leading-edge technologies and open innovation for social transformation



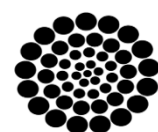
Modelo EFQM, Proceso Hoshin Kanri, Mejora Continua

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Introduction

The present research develops both methodologies, Hoshin Kanri [HK] and EFQM as an improvement strategy in an organization specialized in the production of boxes for medicines for the pharmaceutical industry. The results are encouraging, going from 79.88% to 92.30% customer satisfaction. All organizations are exposed to constant and rapid changes in the social, economic, political and even cultural context, propelling them into an increasingly globalized and complex world. In addition, by developing both methodologies, they provide quality indicators, contributing to the continuous improvement of the entire process.

The challenge of any organization lies in making strategic planning capable of revolutionizing current procedures and giving certainty to quality processes. Each department has goals capable of being achieved with a strategic vision and a focus on quality. The following research proposes a solution to increase customer satisfaction by developing a strategic planning model that includes the EFQM model, considering the use of probability in any teaching-learning process in the innovation of any system as a learning process [Rueda, 2019]. However, the existence of strategic organizational thinking in the field or in practice for decades makes it increasingly complex [Sanabria, 2004]. One of the characteristics of HK and its elements that distinguish it from conventional strategic planning is an expansion from seven to ten steps [Jolayemi, 2008].

The HK methodology refers to the following points: the plans are developed in a systematic way, the progress in the goals by each area within the organization is meticulously supervised, modifications are made to the plans when required, the established goals are achieved, the planning process is standardized carrying out constant improvement within the organizations [Kenyon, 2007].

Currently, the literature highlights the absence of standards and successful examples in the application of Lean, the culture and the work environment make employees could influence how the HK and Lean methodology are carried out. [Gubinelli, Cesarotti, & Introna, 2020].

The purpose of combining both HK and EFQM methodologies is to create a functional model, evaluating long-term activities within the organization, so that a higher level manages the strategic fit of senior management with day-to-day management. [Witcher B. y., 2007]. Hoshin Kanri could be efficiently used to implement tactics and improve top-down matchmaking. This goal needs to be achieved so that experts are properly trained and frontline staff are involved in daily continuous improvement efforts. [MHA & Soliman, 2020]. The EFQM excellence model proves to be an outstanding model as an instrument of systematic self-assessment of an organization, guiding the analysis towards possible parameters of excellence and firmly prioritizing progress in terms of constant improvement.

Therefore, it facilitates the acquisition of a critical vision of the organization's situation, recognizing the potential strengths and areas for improvement within the organization. The EFQM model allows us to self-evaluate and determine "where the organization is and thus where we are going", however, it is necessary to move from reality to a situation of improvement, through inclusion through an action plan and monitoring. Quality management has numerous techniques and tools to facilitate its activities, and is integrated in parallel with other methods of strategic and operational planning, management and administration, to link the realities and needs of an organization.

A methodology that allows a systematization of the objectives of a company/organization in a disaggregated way, with a systematic development and involving the different levels of the organization, is the Hoshin Kanri deployment as a management system of administration by policies. [Balo & Santos, 2004]

The Hoshin planning system, created in Japan after World War II, incorporates management tools specifically designed for the organization of new procedures. There are seven instruments that can be applied individually or in any mix: affinity diagrams, interrelation diagrams, systematic diagrams, matrix diagrams, program charts for process decision-making, arrow diagrams, and prioritization matrices. [D&C, 1995].

Effective planning and long-term strategy are essential to developing a strategic vision within any organization. Lean and Six-sigma are powerful tools of constant improvement that are widely used to increase quality, productivity, profitability and competitiveness in the contemporary market [Agustiady & Cudney A, 2015]. The strategic management model suggested by [HK] suggests harmonizing functions and actions with the organization's most relevant strategic objectives [Santos & V, 2022]. This research suggests developing the stages of the EFQM model: Management, Organization, Execution and Results using and analyzing quantitative and graphical factors as standards of customer satisfaction, among others. In combination with the methodology [HK], the findings are motivating for the quality and customer monitoring department.

However, in order to encourage participation and support for customer service strategies, organizations must invest in personalized communication, training, and recognition systems that ultimately contribute to providing solutions to different departments by contributing to the field of research by contributing to the development of the company's corporate "Corporate Sustainability in Practice" and "Corporate Sustainability in Practice" Recognize the main opportunities and challenges that facilitate strategic customer follow-up activities. [Kabykenova, 2025]

Literature Review

The EFQM model of Excellence has been consolidated as one of the pillars in the administration and has optimised the performance of entities, both European and Spanish and other countries around the world for more than 25 years. In this period, it has established a scheme of improvement at the methodological level, it has been a support in the articulation of systematic mechanisms of improvement in all the essential elements of the administration. The transformation of the paradigm, the change in the social and cultural context, together with the emergence of a faster and more digital world, have demanded that the model not only adapt, but transform to give certainty to the companies of the new century and to the new emerging marketers.

The EFQM model offers a guide to organizations in their persistent desire for excellence. Organizations, both public and private, in health, among others, choose to professionalize their administration through a model that makes it easier for them to evaluate their progress. [Nicolás & Castillo, 2020].

In contrast, there are works that address performance in SMEs, proposing their hypotheses on the functions of resource management and personnel administration with the aim of prioritizing operations in SMEs [BE Narkhede, 2012], one of the works in which the Hoshin Kanri methodology is used. It is based on the process of constant improvement that establishes a relationship between the strategic goal and its application in the daily management of the company [Butterworth, 1999].

One of the upcoming studies that deals with the issue of Hoshin kanri and the critical success factors in quality management and lean production, mentions that strategic planning is an element of TQM/lean production and that its elements are framed in Hoshin [John, 2016]. The integrated management system and the Hoshin Kanri perspective as integrative dynamic skills drive the strategic management process, as noted in his article Balanced Scorecard and Hoshin Kanri: Dynamic Skills for Managing Strategic Fit [Witcher & Sum, 2007].

In contrast to conventional measurement methods, the EFQM model offers the possibility of optimizing the organization's strategies while enhancing business objectives, however, it is effective in evaluating business performance by presenting different optimal tactics for each company, allowing the past, present and future to be analyzed simultaneously, the prevailing opinion indicates that only 10% of companies are able to put into practice their strategies. [Hidroğlu, Self-assessment Performance Measurement in Construction Companies: An Application of the EFQM Excellence Model on Processes and Customer Stages, 2019].

The method [HK] allows us to implement and apply in any area of the organization as mentioned in the work entitled. The Hoshin Kanri planning process in human resource management: hiring in a high-tech company, highlights the relevance of strategic management and enhances its actions to achieve the organization's goals. [Su & Yang, 2015].

Through the transformation and evolution of paradigms and an adequate strategic reorientation, the tree [HK] emerges, which is based on the standardization and learning rhythms for the creation of Industry 4.0 organizations mentioned in the study The HOSHIN KANRI TREE. Lean Shopfloor Management crossplant [Javier Villalba Diez, 2015]. The industrial applications of [HK] have been forced to focus on the Japanese organization as it is the means for implementation over total quality management. [Charles & Paul, 2000].

The interest in applying the Hoshin [HK] methodology in the organization is due to the constant need to establish policies that accelerate work in organizations, as indicated [Lee, 1998]. This study highlights a management management system that facilitates constant progress in the organization, through the development of a plan of policies defined each year.

Methodology

The purpose of this research is to expose the optimal functioning of both methodologies, the Hoshin Kanri and the EFQM model, in a company dedicated to the production of a box for medicine, and to demonstrate their practical application in relation to two phases: returns and delays in deliveries. The EFQM model maintains that customer and employee satisfaction, as well as the impact on society and consumers, can be achieved through leadership that promotes the necessary policies and strategies that strengthen alliances in the different departments of the entity. The EFQM framework represents a reference model for project development. non-prescriptive work based on 9 criteria, which in turn are evaluated. They are segmented into sub-criteria, which can be used to assess performance. An entity's progress towards excellence, since it facilitates the comparison of the current situation of the organization with a theoretically ideal circumstance.

The principles of excellence on which the model is based are: results-oriented; customer orientation; leadership and coherence; management by processes and facts; development and involvement of people; continuous process of learning, innovation and improvement; development of alliances; social responsibility.

The criteria are grouped into 2 blocks as shown in the following [table 1]: facilitating agents [what the organization does and how it does it] and results [what the organization achieves]. [Davins Miralles, 2007]

Box 1

Table 1

Facilitating agents [what the organization does and how it does it] and results [what the organization achieves].

Criteria	Results
Leadership	Results for customers
Policy and Strategy	Results for people
Personnel	Results for society
Partnerships and Resources	Key results
Processes	-

Source: [Davins Miralles, 2007]

Process stage

In the EFQM model, the process phase refers to the optimal design of the organization and management systems through the development of processes with the aim of achieving customer satisfaction and generating considerable value for customers and shareholders. To achieve this phase of process excellence, companies need to design their processes based on policies and strategies based on quality standards. To successfully manage the customer service stage, it is necessary to manage and improve customer relationships. Thus, companies must examine the positive or negative opinions of their customers, including complaints, or negative comments of products on a daily basis, and then they must ensure that their operations, such as sales, advertising and distribution, are updated through exit surveys on product satisfaction to the end customer. A relevant factor to consider in companies is the constant communication between employers and organization, in order to know the current needs of the market.

Customer Stage

One of the nine crucial phases of the EFQM model is the customer phase, where it is possible to carry out a customer-centric performance appraisal. The customer-centric approach has a global influence on the activities of the organization. The crucial step is to realistically set customer expectations and requirements.

To successfully manage the customer service stage, it is necessary to manage and improve customer relationships. Thus, companies must examine the positive or negative opinions of their customers, then companies must establish communication with their customers to increase the added value of their supply chain. Finally, companies have a duty to communicate to their customers about their products in order to increase their recognition. [Hidroğlu, Self-assessment Performance Measurement in Construction Companies: An Application of the EFQM Excellence Model on Processes and Customer Stages, 2019]

Strategic management of the Hoshin kanri [HK]

The Hoshin Kanri is an organizational framework that allows for strategic management within any organization. It is made up of four main tasks which are mentioned below: The first focuses on the organization's attention to corporate management by establishing vital strategic priorities. Secondly, there are the lines with local strategic plans and programs. Third, it is integrated with the management that is carried out daily among employees; Finally, it provides for a detailed structured review of its progress.

A fundamental need for every organization is to carry out the strategy that allows it to be a guide for decision-making, in daily work it is a central concern of strategic management. This is particularly true in the work that emphasizes the importance of organizational transparency for the implementation and self-management of strategic intent.

Hoshin Kanri originated in the 1960s, when the Japanese turned statistical quality control and management into goals. In an integrated modality of organizational management, which they called total quality control and which later spread in the West as total quality management [TQM].

Japan's powerful paper proposed Hoshin Kanri as an essential framework for comprehensive forms of TQM. It is argued that this model provides an organizational and transparent architecture, which is necessary for strategy and daily management to be combined in the use of TQM.

TQM offers the resources and discipline for self-management at any level of administration, not just for managing an operational process in everyday work. An essential component of this is the PDCA cycle, which defines good management as a cyclical process that follows the sequence of planning, performing, verifying, and acting. [Witcher & Butterworth, 1999]

Model Development

The proposal suggests an approach as suggested in his work [Mary Malone, 1995], indicates that the implementation of this plan demands the involvement and cooperation of all employees of the company, including the following four key components.

Mission: The purposes to be achieved are usually competitive in nature. Goals: Indicators of the achievement of goals, which must be set in a very objective way to be measurable.

Strategies: Detail the strategy and method to achieve the established objectives and goals. Execution Evaluation: Establish the progress or competence of the strategy to assess its Execution. [Babich, 2006] An example of the creation is placed on top of the action plan: Hoshin Kanri planning format.

Box 2

Table 2

Description of the main objective

Specific objectives	Setting the objectives
Description of the main objective	
Strategies to achieve the objective.	
Strategy	Objectives
Strategy 1	Objectives
Strategy 2	
Strategy.....n	

Source: Own elaboration

In this part, the appropriate model for the Hoshin Kanri planning system is shown with the aim of knowing the satisfaction of our customers and providing a solution to the problem. Objective: To collect information about current productivity rates, as well as customer satisfaction evaluations. Specifically, the information sought is:

- Causes that affect productivity.
- Dissatisfied customer indicator.
- Causes of customer dissatisfaction

Once the objective to be evaluated through the EFQM model was defined, a work team was formed to carry it out. The duration of the study was 25 days, the development of which is described in the following table.

Box 3
Table 3
Schedule for the month of June 2024

ACTIVITY	June											Responsible
	1	4	5	6	7	8	11	12	13	14		
Cycle planning. Identify and select sources of information.												Author, DO Author, DO
Collection of Information.												Author, DO, P,JP
Information processing.												Author, DO, P, PE
Information analysis. Present results.												Author, DO Author, DO

Source: Own elaboration

The team that was integrated to carry out the application of the methodology was:

1. Author
2. DO – Director of Operations
3. P – Production
4. JP – Planning

Once the planning process of the EFQM model was completed, the process of compiling and evaluating the following indicators began. Two types of indicators were identified to determine current productivity. [Rodríguez & Gomez, 1991]:

Effectiveness in compliance: Through this type of indicator we evaluate the degree of compliance, in terms of the quantity of the product delivered, its general form is the following Ec.1

$$EC = [PR] / PP$$
 [1]

Where the effectiveness of EC. Which is given as the ratio of actual production PR to scheduled production PP

Taking the history of the month of June 2024, we have the following information: The quantity that was scheduled to be produced in that month was 5,001,000 pieces and since the quantity produced in that month was 3,994,872 pieces, we obtain the effectiveness of compliance Ec. [2].

$$EC = [3,994,872] / 5,001,000 = 0.7988$$
 [2]

Which represents 79.88%

Delivery effectiveness: If a product is not finished at the requested time, it cannot meet the customer's needs, being the same as a product with defects.

That is why it is important to control compliance with delivery dates. The indicator to evaluate this type of situation in the delay in delivery, its general form is as follows

$$RE = [N_o E. Delayed] / [N_o E. Performed]$$
 [3]

Where RE represents the delivery delay. Taking the history of a month, we have the following information:

Since the number of deliveries made in that month was 99 and the number of deliveries with delay was 2, the delay in deliveries is Ec. 4.

$$RE = 28 / 99 = 0.28$$
 [4]

This represents a delivery delay of 28%

The instrument that was applied to the seven customers with the highest demand for medicine box products is shown below, and the following results were obtained.

Box 4

Table 4

Information gathering instrument.

Weight	Attribute	Degree of Satisfaction		
		Deficient	Good	Excellent
10%	How do you evaluate the speed of response to quotes?			
10%	How do you evaluate the care received?			
10%	How do you evaluate feedback from your in-process product?			
10%	How do you evaluate the delivery time of your product?			
10%	How do you evaluate the quality of the delivered product?			
10%	How do you evaluate the condition in which you received your product?			
10%	How do you evaluate our company's quality management system?			
10%	How do you evaluate the technical advice provided on your product?			
10%	How do you evaluate the speed and clarity of response to questions and complaints?			
10%	How do you evaluate our company's overall service?			

Source: Own elaboration

We show the behavior graphically the general evaluation of customer satisfaction.

Box 5

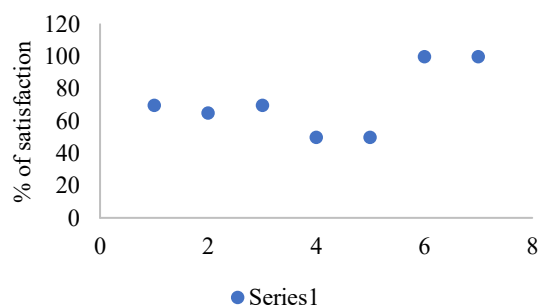


Figure 1

Overall customer satisfaction assessment

Source: Own elaboration

Results

To carry out the proposal for continuous improvement, the results of both methodologies are taken, developing the following innovation system throughout the manufacturing process of the medicine box, as shown below.

Box 6

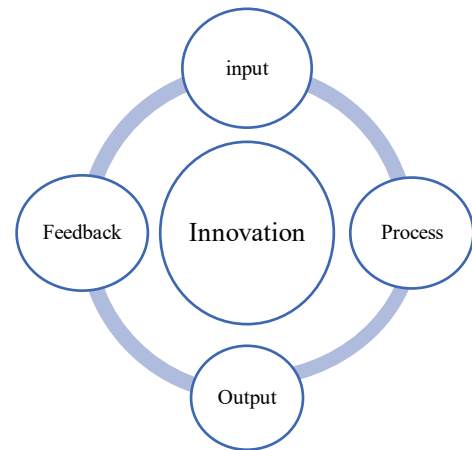


Figure 2

Proposed system including innovation as a strategic factor throughout the process

Source: Source: Own elaboration

The conventional manufacturing system was restructured, following up on the management proposal where the term innovation is integrated. Those responsible for the manufacturing area implemented the process in the manufacture of the medicine box, complying with the customer's requirements and thus reducing delays.

The next stage consists of selecting, collecting and processing the different sources of information. Information can be divided into two types: primary and secondary.

Primary information is information that has not been processed and that can be obtained directly from interviews, observation and experimentation. On the contrary, secondary information is that which has already gone through a previous processing or interpretation as shown in the following process where both methodologies are implemented.

Box 7

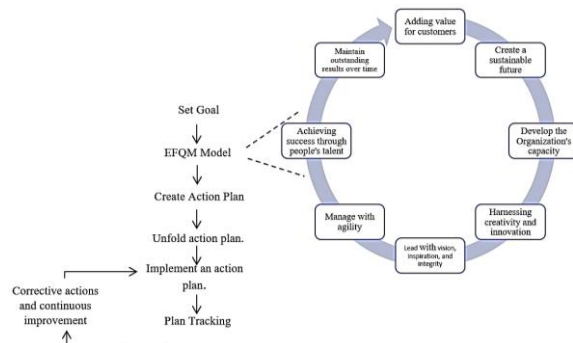


Figure 3

Integration of the EFQM model

Source: Source: Own elaboration

Information collection and analysis

Setting the key objective is the first step. The company's objective was analyzed and its elements were prioritized. In this case, it was not necessary to carry out the affinity diagram proposed in the methodology, because the company is clear about its key objective: To be a highly profitable, productive company with a high degree of commitment to the customer.

Its focus is on the area of quality. The particular element of the key objective is aimed at satisfying the company's potential customers, and in a cascading way it seeks to provide results to other customers, providing product satisfaction.

Box 8

Table 5

Validation of the instrument using Cronbach's Alpha

Respo ndents	ITEMS										addi tion
	1	2	3	4	5	6	7	8	9	10	
E1	5	2.5	5	5	5	5	5	5	2.5	2.5	40
E2	2.5	2.5	2.5	5	5	5	5	5	2.5	2.5	37.5
E3	2.5	5	5	5	5	5	5	5	2.5	5	45
E4	5	5	2.5	5	5	5	5	2.5	2.5	5	42.5
E5	2.5	2.5	2.5	5	5	5	5	2.5	2.5	2.5	35
E6	2.5	2.5	2.5	5	5	5	5	2.5	2.5	2.5	35
E7	5	5	2.5	5	5	5	5	5	5	5	45
Varia nce	1.5 31	1.5 31	1.2 76	0.0 00	0.0 00	0.0 00	0.0 00	1.5 31	0.0 00	1.5 31	
summat ion of varianc es	4.337										
variane e of the sum of the items	16.071										

Source: Own elaboration

The instrument provided us with a confidence coefficient of 81.12%, in a range of excellent confidence.

Box 9

Table 6

Validation of the instrument using Cronbach's Alpha

Questionnaire coefficient	reliability	0.811
Number of items in the instrument		10
Summing the variances of the items		4.33
Total Instrument Variance		16.07
RANGO		RELIABILITY
0.53 Menos		Zero reliability
0.54 a 0.59		Low reliability
0.60 a 0.65		Reliable
0.66 a 0.71		Very reliable
0.72 a 0.99		Excellent reliability
1		Perfect reliability

Source: Own elaboration

The following graph shows an increase in deliveries, by applying both EFQM methodologies it will be possible to obtain 99% satisfaction in the not too distant future, applying actions in conjunction with senior management, by integrating Hoshin Kanri [HK], as shown in November of this year.

Box 10

Customer Satisfaction
November 2024

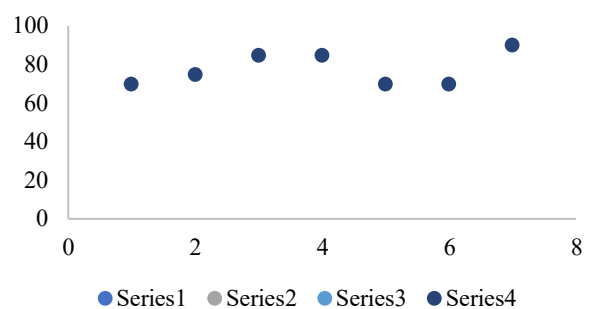


Figure 4

Customer satisfaction evaluation.

Source: Own elaboration

The quantity that was scheduled to be produced in the month of November was 6,500,000 pieces.

The quantity produced in that month was 5,999,892 pieces, thus representing an effectiveness of compliance with Ec.5

$$EC=5,999,892/6,500,000=0.9230$$
 [5]

Which represents 92.30%.

Delivery effectiveness: If a product is not finished at the requested time, it cannot meet the customer's needs, being the same as a product with defects. That is why it is important to control compliance with delivery dates.

On the other hand, taking the history of one month we obtain the delay in deliveries. We have that the number of deliveries made in that month was 99.

The number of late deliveries was 19 therefore we get.

$$RE=19/99=0.1919 \quad [6]$$

This represents a percentage of delivery delay of 19.19%.

Thus, by combining both methodologies, the delay in the deliveries of boxes for medicine was reduced, at the same time the effectiveness in compliance being 92.30%, achieving a comprehensive continuous improvement throughout the organization, undoubtedly a great collaborative and managerial effort.

Discussion of results

The Integration model, which improves the production process of medicine boxes in an SME under both Hoshin Kanri methodologies, and EFQM, as an improvement proposal, integrating senior management as the main part in the implementation of a strategic vision, with clear objectives in the short and medium term giving certainty of compliance considering the following factors to be evaluated: Returns and delays in deliveries, the results presented are encouraging, going from 79.88% compliance to 92.30% satisfaction, and consistently lowering the rate of delay in deliveries from 28% to 19.19%, when applying both EFQM methodologies and integrating Hoshin Kanri [HK], the cycle of continuous improvement is enhanced as a factor of change in the system, giving priority to customer satisfaction, through the cycle [PDCA], feedback will be sought through a strategic approach allowing the inclusion of all the personnel of the organization, achieving results in the short term.

The implementation of both methodologies in the business planning process generated a broad understanding of the context, simplified data collection; in addition, it made it possible to develop and execute an action plan, in accordance with the main purpose of the organization. This action plan, apart from being detailed on a large scale, was suggested by the entire team. Thus, each goal and each goal was met considering the observations and contributions of all.

During the execution of the plan, a greater commitment of the participants was noticed, since they understood the relevance of the strategies defined to achieve the objectives set.

As a result, aspects of improvement were incorporated throughout the process, as an effect of inclusion of all the organization's employees. This allows strategic actions to be planned in advance not only in the present but also in the future.

Conflict of interest

The authors declare no interest conflict. They have no known competing financial interests or personal relationships that could have appeared to influence the article reported in this article.

Authors' Contribution

The contribution of each researcher in each of the points developed in this research, was defined based on:

Dorantes-Benavidez, Humberto: Contributed to the project idea, research method and technique. He supported the design of the field instrument. He carried out the data analysis and systematisation of results, as well as writing the article.

Gutiérrez-Lugo, Lucia Monserrat: Carried out the systematisation of the background for the state of the art. She supported the design of the field instrument. She also contributed to the writing of the article.

Martínez-Cruz, Miguel Ángel: contributed to the research design, the type of research, the approach, the method and the writing of the article.

Article

Núñez-Martínez, Gisela: worked on the application of the field instrument, data collection and systematisation of the results. He also worked on the writing of the paper.

Availability of data and materials

The images shown within the document were results of the research presented therein, with the data collected and the background of the same were developed.

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The research did not receive any funding.

Abbreviations

EFQM	European Foundation for Quality Management
GCT	Total quality management
PR	Scheduled production
RE	Delayed deliveries

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Antecedents

Rueda, S. A. [2019]. [Modelo TPACK: ¿Medio para innovar el proceso educativo considerando la ciencia de datos y el aprendizaje automático?](#) *Entreciencias: diálogos en la sociedad del conocimiento* , 50-60.

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