

DYNA

ISSN: 0012-7353 ISSN: 2346-2183

Universidad Nacional de Colombia

Sanchez-Lizarraga, Marcos; Limon-Romero, Jorge; Tlapa, Diego; Baez-Lopez, Yolanda ISO 9001 Standard: exploratory analysis in the manufacturing sector in Mexico DYNA, vol. 87, no. 213, 2020, April-June, pp. 202-211

Universidad Nacional de Colombia

DOI: https://doi.org/10.15446/dyna.v87n213.83230

Available in: https://www.redalyc.org/articulo.oa?id=49664596027



Complete issue

More information about this article

Journal's webpage in redalyc.org



Scientific Information System Redalyc

Network of Scientific Journals from Latin America and the Caribbean, Spain and Portugal

Project academic non-profit, developed under the open access initiative







ISO 9001 Standard: exploratory analysis in the manufacturing sector in Mexico

Marcos Sanchez-Lizarraga, Jorge Limon-Romero, Diego Tlapa & Yolanda Baez-Lopez

Facultad de Ingeniería, Arquitectura y Diseño, Universidad Autónoma de Baja California, Ensenada, Baja California, México. msanchez68@uabc.edu.mx, jorge.limon@uabc.edu.mx, diegotlapa@uabc.edu.mx, yolanda@uabc.edu.mx

Received: August 29th, 2019. Received in revised form: March 17th, 2020. Accepted: April 16th, 2020

Abstract

The purpose of this research is to provide a current situation of the ISO 9001 standard in the manufacturing sector in Mexico, identifying the critical success factors, barriers and benefits of its implementation. A survey with 55 items in a five-point Likert scale, mainly focusing on quality managers, was used and was provided by e-mail and the social network LinkedIn, which obtain 172 complete responses. The ISO 9001 standard is one of the initial strategies to manage quality; however, the results exhibit some barriers that hinder its implementation. According to the seven quality principles for the implementation of the standard established by the International Organization for Standardization, the results showed that leadership and customer focus are the main factors to satisfactorily adopt the standard in the manufacturing sector in Mexico, and this helps the industry to achieve some benefits.

Keywords: quality management; ISO 9001 standard; critical success factors; survey; manufacturing sector.

Estándar ISO 9001: análisis exploratorio en el sector manufactura en México

Resumen

El objetivo de esta investigación es proporcionar una situación actual del Estándar ISO 9001 en el sector de manufactura en México identificando sus factores críticos de éxito, barreras y beneficios de su implementación. Se utilizó una encuesta con 55 ítems en una escala Likert de cinco puntos centrada principalmente en gerentes de calidad y distribuida por correo electrónico y la red social LinkedIn obteniendo 172 respuestas completas. El estándar ISO 9001 es una de las estrategias iniciales para gestionar la calidad, sin embargo, los resultados muestran algunas barreras que dificultan su implementación. De acuerdo con los siete principios de calidad para la implementación del estándar establecida por la Organización Internacional de Normalización, los resultados revelaron que el liderazgo y el enfoque al cliente son los principales factores para una adopción satisfactoria de la norma en el sector manufactura en México que ayuda a esta industria a lograr algunos beneficios.

Palabras clave: gestión de la calidad; estándar ISO 9001; factores críticos de éxito; encuesta; sector de manufactura.

1. Introduction

The quality of products or services is a reflection of company's ability to improve by process management [1]. The accomplishment of a quality product or service is the reason why quality management systems (QMS) have been created or improved to assure this characteristic, and at the same time, achieve customer satisfaction. The usage of a QMS is fundamental to support an organization's

performance, providing a range of benefits for improvement; thus, it has a positive effect on organizations [2]. The literature shows many QMSs that are related to attainment of quality in products or services, such as Total Quality Management (TQM), the Malcolm Baldrige National Quality Award (MBNQA), European Foundation for Quality Management (EFQM), Six Sigma (SS), Lean Manufacturing (LM) and the ISO 9001 standard, among others. The main focus of this research is the international ISO 9001 standard,

How to cite: Sánchez-Lizarraga, M, Limón-Romero, J, Tlapa, D. and Baez-López, Y, ISO 9001 Standard: exploratory analysis in the manufacturing sector in Mexico. DYNA, 87(213), pp. 202-211, April - June, 2020.

created by the International Organization for Standardization (ISO). The most recent version of the standard is the ISO 9001:2015, which focuses on the adequate management of activities in order to accomplish and exceed customer requirements [3].

The ISO 9001 standard is by far the most implemented and recognized QMS and helps companies to achieve continuous improvements; hence, the standard allows for the guidelines to improve the operational systems of the company. According to the requirement manual of the ISO 9001:2015, the standard is a set of almost 20 complementary standards that provide the theoretical and practical support in almost all the functional areas of an organization for the accomplishment of regulatory requirements and customer requirements.

In this respect, the objective of this paper is to recognize the current situation of the ISO 9001 standard and its critical factors, which allows for the implementation of the standard in the manufacturing sector in Mexico (MSM). To achieve this objective, a survey was first designed to collect data, and secondly, a statistical analysis was carried out to describe the current situation of the standard in Mexico.

2. Literature review

2.1. ISO 9001 standard review

The International Organization for Standardization was founded in 1947 and has created over 21,000 international standards, covering almost all aspects of technology and manufacturing [4]. The first ISO 9000 series from the international quality management standards was published in 1987, and was created to enable a mutual understanding of quality requirements in national and international trades [5]. The ISO 9001 standard defines what the business should do to consistently provide products that meet customer expectations and applicable statutory and regulatory requirements. In addition, businesses will seek to enhance customer satisfaction by continuous improvement of the QMS, regardless of the size or industry type [6].

The ISO 9001 standard uses three approaches as the bone structure of its functionality: (1) Process Approach, which incorporates the PDCA cycle (Plan-Do-Check-Act), enabling an industry to plan the process related to its resources and internals interactions; (2) Risk-Based Thinking, which enables an industry to find circumstances that could cause troubles or malfunctions in the QMS placing preventive controls to minimize negative effects, and also ensures the maximum usage of opportunities as they occur; and (3) the Seven Quality Management Principles (QMPs) [7,8]. Likewise, Heuvel [9] detailed how the standard takes the process approach to improve organizational and financial performances with a specific focus on quality management, process control and quality assurance techniques in order to achieve planned outcomes and to prevent unsatisfactory performance or non-conformance.

The reviewed literature exhibits a variety of concepts

concerning the standard. For example, [10] describes the ISO 9000 series as a basic standard used for external quality assurance purposes and is designed for internal use focusing on quality aspects consistency in the production of a product or service. Uzumeri (1997), cited by [11], defined the ISO 9001 standard as the most prevalent management standard certification, spanning a variety of industries. Anttila and Jussila [12] mentioned that the starting point in implementing the ISO 9001standard should be the organizational needs related to the QMS, and [13] described the performance of the standard as including long term contributions and potentially positive, neutral or negative effects, depending on the company's objective. According to [14], the standard is a provider of an excellent framework that empowers the company to develop a customized OMS to facilitate the optimal deployment of valuable resources into its key processes. In addition, [15] describes the ISO 9001 standard, in the context of Small and Medium Enterprises (SMEs), as one of the legitimation strategies to cope with external pressure and to overcome the liabilities of newness and smallness. Additionally, the ISO 9001 standard is considered to be the first step to develop a QMS and encourages companies to incorporate a continuous improvement culture [10,16-20].

The ISO 9001 standard is a set of formalized processes to evaluate the ability of any organization to consistently design, produce, and deliver quality products and services. This standard provides an important contribution to achieving improved product/service performance [21]. None of the guidelines of the standard contain requirements or acceptance criteria for a product; that is, the standard cannot inspect a product against the standard terms and guidelines. Therefore, the main interest of the ISO 9001 standard is only the QMS of the business [5].

Since the standard update in the year 2000, the ISO began to use the term "principle" as a basic belief, theory or rule, and this has a major influence on the way in which an activity is done. In this case, the OMPs are sets of fundamental beliefs, rules and values that can be used as a basic template or guideline for a QMS to accomplish performance improvement [22]. Taking the idea from [23], these principles can be theorized as the essential components or characteristics that must be achieved by any industry or business in order to produce the greatest advantages and to complete the implementation of the ISO 9001 standard. Organizations trying to implement a QMS continuously seek to identify factors that are believed to be critical for successful implementation. These factors are often defined as Critical Success Factors (CSFs). The CSFs can be theorized as the essential elements that the business must align for successful QMS implementation [2]. Some authors report different factors in the implementation of the standard [13,16,24-26]; however, the CSFs reported essentially match the QMPs. Consequently, these elements can be recognized as CSFs that simplify or empower the adequate implementation of the standard in an industry or business. Below is a list of QMPs (CSFs) and their definitions based on [27] and [7]:

Leadership (LD): Leaders at all levels establish unity of purpose and direction and create the conditions in which people engage the business's objectives.

Customer Focus (CF): Primary focus of quality management is the satisfaction of customer requirements and the effort to exceed their expectations.

Engagement of People (EP): Essential for the business that people are competent and empowered at all levels to enhance its capability to create and deliver value.

Process Approach (PA): Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Improvement (IMP): Successful businesses have an ongoing focus on improvement.

Evidence-based Decision Making (EDM): A decision based on the analysis and evaluation of data is more likely to produce desired results.

Relationship Management (RM): For sustained success, a business manages its relationships with interested parties.

2.1.1. ISO 9001 barriers and benefits

Some obstacles prevent the development of the standard. Santos et al., [28] described how these barriers can be associated with a lack of focus on the critical factors for an adequate implementation. The literature classifies the most common barriers in two ways: the barriers related to leadership and those related to the engagement of people. Destitute leadership carries problems such misunderstanding ISO 9001 standard requirements, lack of communication between the business areas, financial issues, lack of strategic thinking, poor auditing systems, stationary issues and lack of a continuous improvement focus [29-31]. Barriers related to the engagement of people creates problems such as: lack of cooperation and involvement of people, lack of discipline following new work methods, resistance to change, insufficient training and lack of motivation to improve [32,33]. Another barrier reported is the large time needed for implementation, since some business do not have time to develop this kind of project or the business resources are limited to a very short amount of time [33,34]. Additionally, [31] mentions that the paper work bureaucracy within the business and procedures could stop the fluency of information and decision-making in some

In the context of benefits, the literature consulted reports that these can be acquired by implementing the ISO 9001 standard in all types of businesses or industries. For example, [35] reported a decrease in manufacturing times and the redesign of pieces to reduce waste, which means an increased improvement to the business' quality system. Moreover, some authors describe how the quality management achieved by the ISO 9001 standard addresses the business to work with TQM [13,20,25]. Some benefits of the ISO 9001 standard are related to the improvement in the manufacturing systems, which leads to the production of quality products, as well as the productivity of the business increasing [33,36,37].

Additionally, [38] described how the ISO 9001 standard improves the speed of services and reduces customer complaints related to banking services. In addition, [39] describes how the SMEs food enterprises can achieve some benefits by implementing the ISO 9001 standard, such as continuous improvement, prevention of nonconformities and customer satisfaction focus. Some authors [30,40,41], agree that a business acquires wide competitive characteristics, which means that the effectiveness of its systems increase the profits, and described how the benefits are related to the effective implementation of the standard; in other words, the organization must maintain the benefits acquired by the standard as long as the organization develops and practices a continuous improvement that focus on increasing profit and productivity. Likewise, [33,37,42] described that, when the industries increase productivity, customer complaints tend to minimize, and as a result, customer satisfaction is improved. Customer satisfaction is synonymous to better customer service, which means the business is accomplishing as many requirements, asked for by the customer, as possible. Additionally, the business involves the customer feedback to improve its systems and services; performance in customer satisfaction may strengthen business relationships that encompass and reach new market shares and marketing tools [12,43]. Another study by [44] describes 20 benefits that are acquired by SMEs in Soudi Arabia, such as: (1) increased quality awareness, (2) efficiency improved in the quality system and quality products, and (3) improved customer service, to mention a few. Dowlatshahi [45] defines how the ISO certified companies placed more emphasis on the relationship with main suppliers in a management supply chain system, obtaining more competitive advantages than those that were not certified, which tended to place more emphasis on price and delivery issues.

The literature reported a variety benefits that were developed by the implementation of the ISO 9001 standard, as well as many barriers that preclude its implementation; however, no literature on these topics was found in the MSM, which represents a lack of information in this context. Hence, this research will analyze the data acquired related to barriers and benefits perspectives, in order to acknowledge the current situation in the MSM.

2.2. ISO 9001 in the manufacturing sector in Mexico

Recently, the ISO survey of Management System Standard Certification [46] reported more than 400,000 organizations certified with ISO 9001:2015 worldwide, of which 2,577 were in Mexico. In accordance with this information, Table 1 represents the subsector classification certified with the ISO 9001:2015 standard in Mexico.

The MSM is the second greatest contributor to the Gross Domestic Product (GDP) after the primary activities sector, and has the lowest annual rate of variation of all economical sector in the country, as reported by the National Institute of Statistics and Geography (INEGI, for its acronym in Spanish) [47]. According to the National Statistical Directory of Economic Units (DENUE, for its acronym in Spanish) [48],

nearly 36,000 manufacturing industries exist and are classified as SMEs and large companies. It is worth mentioning that, in this paper, the SME classification is the one used in Mexico. Finally, data from the Economic Ministry [49] mentioned that until 2012, 1,442 manufacturing industries, certified in ISO 9001:2008 in Mexico, existed, but unfortunately, this database is not currently operational. Additionally, [46] shows the number organizations with ISO 9001 standard from 2010 to 2017 in North America (United States, Canada and Mexico), as shown in Fig. 1.

In the first period of time from 2010 to 2013, an increase in the number of certified organizations can be seen in three countries where, in 2013, the highest number of certified organizations was in the United States and Canada. In the second period of time from 2014 to 2017, Mexico had a remarkable increase, with a tendency to keep growing, while in the United States and Canada, a decrease in the number certified organizations can be observed, where 2017 registered the lowest number of organizations certified.

Table 1. Manufacturing subsectors certified with ISO 9001:2015 standard in Mexico.

Manufacturing Subsector	Quantity
Basic metal and metal products	634
Electrical and optical equipment	376
Chemicals, chemical products and fibers	313
Rubber and plastic product	288
Food products, beverage and tobacco	148
Machinery and equipment	146
Pulp, paper and paper products	97
Other transport equipment	83
Textiles and textile products	57
Pharmaceuticals	44
Leather and leather products	12
Manufacture of coke and refined petroleum products	9
Wood and wood products	8
Aerospace	3

Source: ISO Survey 2018.

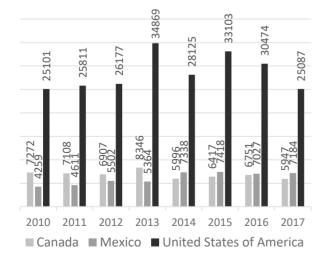


Figure 1. ISO 9001 standard certifications in North America. Source: ISO Survey 2018.

This resembles the results of [50], which identifies a perspective for certification growth of most countries, with the exception of the United States and Canada mainly after the revision of the standard in the year 2000.

The ISO/TC 176 Technical Committee (TC) on quality management and quality assurance has been a leader in the development of standards in the field of OMS since 1979. The TC 176 develops standards through its three subcommittees (SC), which are responsible for the development and maintenance of the ISO 9001 standard, as well as all adjacent standards within the ISO 9000 series [51]. In Mexico, the management of the standard comes directly from the General Direction of Standardization (DGN, for its acronym in Spanish), which is an internal institution of the Economic Ministry responsible for arranging the Mexican Norms (NOM) in order to coordinate the standardization and conformity assessment systems to promote competitiveness of the industry and commerce in a national and international approach. The DGN, with The Mexican Institute of Standardization and Certification (IMNC, for its acronym in Spanish), created the NOM series NMX-CC-9001-IMNC-2015, which is in accordance with the ISO 9001:2015 standard in every guideline established by the ISO.

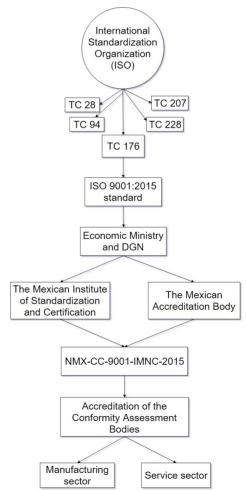


Figure 2. ISO 9001 standard management in Mexico. Source: The Authors.

The Mexican Accreditation Body (EMA, for its acronym in Spanish) is a private institution that is responsible for the accreditation of the Conformity Assessment Bodies to evaluate and certify the business once it accomplishes the requirements of the ISO 9001 standard. Fig. 2 shows a representative diagram of the standard management in Mexico.

3. Method

The target population for the study consisted of the manufacturing industries in Mexico that have or have had the ISO 9001 standard certification, preferably in the 2008 or 2015 version, within the SMEs and large company classification. The study relayed the survey made for this research, based on the literature, with 55 items in a five-point Likert scale (1: never, 2: rarely, 3: regularly, 4: almost always, 5: always) that was related to the level of use of each OMP. This survey was divided in four main sections: the first section with 10 items for demographic data; the second corresponded to the items for the OMPs (7 items for LD, 4 items for CF, 6 items for EP and PA and 5 items for IMP, EDM and RM); the third section had 7 items related to benefits; and the last section had 7 items that were associated with barriers. The survey was mainly focused on quality or manufacturing managers; however, any personnel with a position of middle management, related to the QMS of the organization, could respond. Likewise, the sample size was calculated using eq. (1), which considered a finite population. To do this, a population (N) of 37,148 SMEs and large companies, established in Mexico at the time of the study, was used according to [46]. Additionally, a 99% confidence level (Z_a) and a 50% sample proportion (p), and therefore, an equivalent value for q were considered. Finally, a 10% error margin (i) was used to obtain a sample size (n) of 166 responses. The survey was shared by e-mail and the social network LinkedIn, obtaining 537 responses; however, a total of 172 complete responses were used in the study to accomplish the required data for significant results at this

level of confidence.

$$n = \frac{Z_{\alpha}^2 Npq}{i^2(N-1) + Z_{\alpha}^2 pq} \tag{1} \label{eq:norm}$$

4. Results

4.1. Demographic data analysis

First, Fig. 3 shows the participation percentage in the study by states in Mexico. The principal states with the major participation in the study were Baja California, at 22.10%, follow by Mexico State at 16.90% and Nuevo Leon at 8.70%. According to [48], more manufacturing industries exist in Nuevo Leon, Mexico State and other states than Baja California; however, the geographic location of the authors in this state facilitated the required data.

Regarding the participation of the sub-sectors in the MSM, Fig. 4 shows that the larger percentage of answers were obtained from the machinery and equipment sector, represented as 19.20%, and by the metallic industries and derivatives from petroleum and coal, chemical industries from plastic and rubber, which represented 15.70%. Then, food products, beverages and tobacco represented 15.10%. Finally, the textile industries, clothing and leather industries and paper, printing and related industries contributed 5.20% and 2.30%, respectively. According to these results, the metallic industries and its derivatives from petroleum and coal, chemical industries are the most encouraged manufacturing sectors to achieve the ISO 9001 standard certification in Mexico, which is in accordance with the results of the [46], as displayed in Table 1, as the sectors with more certification acquired. However, food products, beverages and tobacco and machinery and equipment industries have a high percentage of participation in Table 1; meanwhile, the quantity of certified industries in the MSM is not that remarkable. It should be noted that the sub-sectors classification of the MSM in Fig. 4 is the one established by

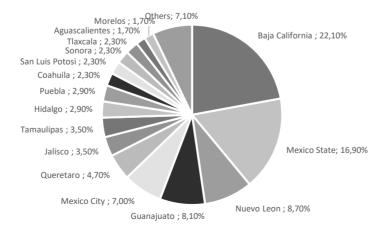


Figure 3. Responses by state. Source: The Authors.

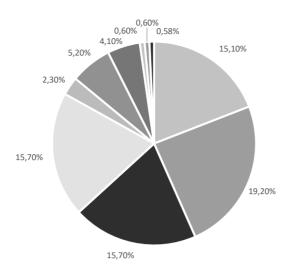


Figure 4. Responses by manufacturing sub-sector Source: The Authors.

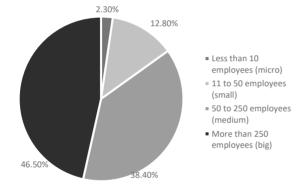


Figure 5. Responses by industry size Source: The Authors.

Furthermore, Fig. 5 represents the industries, certified by size, where large companies identified have higher participation ratios, with 46.50%, followed by medium industries at 38.40%, small industries at 12.80%, and finally, micro industry at 2.30%. Even though this last sector was not the subject of this study, the authors decided to exhibit this result to show the considerations of this kind of company to implement QMS in order to meet customer satisfaction. Finally, these results should be expected, since in the MSM, most of the companies belong to the SMEs and large company sector, according to [48].

4.2. CSF analysis

Table 2 shows the median value, based on the Likert scale previously described, along with the mean and standard deviation (SD) of each factor. LD and CF, with median value of 5, can be considered to be the most significate and

- Food products, beverages and tobacco
- Machinery and equipment
- Derivatives from petroleum and coal, chemical industries from plastic and rubber
 Metallic industries
- Products based on non-metallic minerals
- Textile industries, clothing and leather industries
- Paper, printing and related industries
- Wood Industry
- furniture and related products
- Other manufacturing industries

Table 2.
Implementation factors for ISO 9001 standard in MSM

Factor	Median	Mean	SD
LD	5	4.110	1.118
CF	5	4.327	1.034
EP	4	3.732	1.097
PA	4	4.078	1.077
IMP	4	4.136	1.039
EDM	4	3.991	1.070
RM	4	3.848	1.189

Source: The Authors.

important factors in the MSM; however, the remaining factors have a median value of 4; therefore, these factors should not be considered less important since some relation between them could exist that generates the essential characteristics for a successful implementation of the ISO 9001 standard, considering the attainment of more data.

4.3. Barriers and benefits analysis

In the context of the barriers that limit or prevent the implementation of the standard in the MSM, Table 3 shows the results attained. It should be noticed that the questions about this topic were not obligatory; thus, from the 531 responses, only 40 participants described the reasons why their companies do not work under this QMS. The results showed that the main barrier was customers not demanding the industry to work under the guidelines of the standard representing 35%. Another barrier mentioned was the high investment representing 15%. Then, participants described the industry as managing a better QMS than the ISO 9001 standard, representing 10%, and, taking the business line of the industry into account, the standard became unnecessary representing 10%. Additionally, the results showed that the bureaucratic paper work of the standard into the flow of information within the industry restricted the implementation

Table 3. Implementations barriers for ISO 9001 standard in MSM

Barriers	Percentage
Not demanded by the customers	35%
High investment	15%
The company manages a better QMS than ISO 9001	10%
Unnecessary for the industry	10%
Bureaucratic paper work	7.50%
Other reasons	9.50%
Unspecified	13%

Source: The Authors.

Table 4. Benefits of the ISO 9001 standard

Benefits	Percentage	Frequency
Increase in customer satisfaction	72%	108
Reduction of errors/defects	71%	107
Continuous improvement culture integration	67%	101
Decrease in scrap/activities that do not add value	59%	88
Efficiency in decision making by management	56%	84
Increase in sales	50%	75

Source: The Authors.

of the standard representing 7.50%. Finally, 9.50% described reasons differently from those included in the survey and the remaining 13% did not specify or select any response.

However, Table 4 presents the benefits obtained by the implementation of the ISO 9001 standard. The percentage of each benefit is related to the number of times it was selected in the survey, considering that each participant could select more than one benefit. According to the information, the benefit with the highest amount of mentions is the increase in customer satisfaction mentioned 72% of the time, besides, 71% of participants emphasized that the reduction errors/defects is another benefit that is obtained by implementation. Another benefit that stands out is integration into the culture of the continuous improvement representing 67%, and, the participants also mentioned the waste or the non-value-added activities of products or services are diminished representing 59%. Finally, the efficiency in decision-making by management and increases in sales are two benefits obtained by the standard implementation mentioned 56% and 50% of the time, respectively.

5. Discussion

In the context of industry size, some similar results were reported in [8,52,53], describing size as an influencing factor in the decision to achieve the ISO 9001 standard, even for [54] the size of a company, which certainly influences the implementation of the QMS, where large companies obtain better results with greater tolerance to changes from the introduction and the subsequent maintenance of the QMS. Additionally, Stainslaus et al., [55] described how the SMEs should learn from the QMS used by large companies.

According to the CSF, the results reported in the literature resembles those obtained in this study. For example,

[8,55,56] described top management leadership as one of the main characteristics to arrange a QMS into the organization procedures developing goals and objectives. Further, [57] described how top management leadership and the engagement of people provides for the implementation of the standard. In the same matter, [58] showed that the customer focus, human resources management and the strategic planning of the quality should have the highest consideration when implementing the standard. Finally, [59] revealed that the industries certified in the ISO 9001 standard have an excellent relationship management, and, the organization with engaged personnel also, significantly facilitates the accomplishment of the standard guidelines.

Similar results in the context of barriers were obtained by [60], which described the standard as a beneficial tool for the industry, but at the same time, turns to bureaucratic and complex procedures, which demotivates top management to start the implementation of the standard. Additionally, [61] mentioned that the bureaucracy of the standard in the process, the lack of interest of the management, the high investment and the long time required for its implementation are some of the obstacles and limitations in application. Furthermore, [62] mentioned how the lack of commitment by top management and the financial or resource limitations preclude the assessment of the standard. According to the results, the high investment required and the bureaucracy style of the standard are barriers to implement the standard in the MSM, which resembles the one reported in the literature; however, the lack of demand of the ISO 9001 certification by customers is not reported in the literature as a barrier, while in Mexico, according to the data obtained, this is the main barrier of manufacturing companies not implementing the standard.

The results related to the benefits agree with the findings in the literature, for example, [33,36,39,42], which described how the implementation of the standard increases customer satisfaction and productivity of the company. Likewise, [35,37,44] reported that, when implementing the standard, the integration of the continuous improvement in the company is developed, increasing productivity into the work systems and errors and waste are reduced, thus increasing the benefits. Finally, [63] described the adaptation of the standard to improve the efficiency of operations and marketing strategies, increasing the commitment of people with the accomplishment quality and transforming the organization to work as a synchronized system in order to fulfill the enterprise's goals.

6. Conclusion

As was previously mentioned, the objective of this research is to recognize the current situation of the ISO 9001 standard in organizations in the manufacturing sector in Mexico taking SMEs and large companies as a reference. This research was focused on describing the critical success factors, as well as the benefits and barriers, which are associated with the implementation of this standard in this

kind of organization. According to the literature consulted, the ISO 9001 standard is recognized worldwide as a quality management system that allow companies to implement possible improvements into the quality processes, fulfilling expectations of clients and at the same time profiling the organizations towards continuous improvement. In this sense, it could be mentioned that the implementation of the ISO 9001 standard in the MSM is, nowadays, one of the primary strategies to manage quality and to accomplish clients' requirements, mainly in large companies and machinery and equipment sectors, as was stablished in the aforementioned results.

Additionally, this work also remarked that the recognition of the CSFs for the ISO 9001 standard as the essential elements that must be accomplished for its successful implementation. The CSFs could be mentioned as a basic task to facilitate the standard's adoption, and consequently, to get the benefits it could provide, highlighting an increase in customer satisfaction, the reduction of errors or defects, and also the integration of a culture that is based on continuous improvement as was most frequently reported by the surveyed personnel. If this is adequately managed, it could be converted into competitive advantages. In this case, the leadership and customer focus were found to be the most important factors for the adequate and successful implementation of the ISO 9001 standard in the MSM. In other words, top management should lead the continuous improvement of the company, based on wise decisions, to ensure the engagement of employees to comply with work processes and to always focus on customer satisfaction.

Additionally, some barriers that are difficult for the adoption of the standard were analyzed, and according to the results, the lack of demand by customers to work with the ISO 9001 standard is reported to be the main barrier that could lead to organizations not seeking adoption. Therefore, because of the existence of these barriers, the adequate identification of the CSF is highly important because, by focusing on these key elements, the negative effects of the barriers could be counteracted, thus increasing the probability of a successful implementation, and so, access to the corresponding benefits.

Finally, a model could be fitted to define the relationships among CSFs and potential benefits that were reported in this research; hence, future research should focus on analyzing the factors in developing a Structural Model to help decision-makers determine the activities and actions that must be undertaken to facilitate the adoption of this still broadly used standard.

References

- [1] Elzinga, D.J., Horak. T., Lee, C.Y. and Bruner, C., Business process management: survey and methodology. IEEE Trans Eng Manag., 42, pp. 119-128, 1995. DOI: 10.1109/17.387274.
- [2] Garza-Reyes, J.A., Rocha-Lona, L. and Kumar, V., A conceptual framework for the implementation of quality management systems. Total Qual Manag Bus Excell., 26, pp. 1298-310, 2015. DOI: 10.1080/14783363.2014.929254.
- [3] Wecjenmann, A., Akkasoglu, G. and Werner, T., Quality managment

- history and trends. TQM J., 27, pp. 281-293, 2015. DOI: 10.1089/can.2016.0016.
- [4] International Organization for Standardization. ISO The ISO Story. [online]. n.d. [accessed: October 23, 2019]. Available at: https://www.iso.org/the-iso-story.html
- [5] Salagean, H.C., Gârbacea, R.D., Emmanouilidis, E. and Marian, O., From ISO standards to TQM philosophy. Manag Challenges Contemp Soc., 7, pp. 93-98, 2014.
- [6] International Organization for Standardization. Selection and use of the ISO 9000 family of standards, 2016.
- [7] Manders, B., De Vries, H.J. and Blind, K., ISO 9001 and product innovation: a literature review and research framework. Technovation, 48-49, pp. 41-55, 2016. DOI: 10.1016/j.technovation.2015.11.004.
- [8] Farinha, L., Lourenço, J. and Caroço, C., Guidelines for the Implementation of a Quality management system in industrial companies. Rom Rev Precis Mech Opt Mechatronics., 1, pp. 195-201, 2016.
- [9] Van Den H.J., The Effectiveness of ISO 9001 and Six Sigma in healthcare. Alphen Aan Den Rijn: Erasmus University Rotterdam; 2007.
- [10] Zhu, Z., A comparison of quality programmes: total quality management and ISO 9000. Total Qual Manag., 10, pp. 291-297, 1999. DOI: 10.1080/0954412998018.
- [11] Gray, J.V., Anand, G. and Roth, A.V., The influence of ISO 9000 certification on process compliance. Prod Oper Manag., 24, pp. 369-82, 2015. DOI: 10.1111/poms.12252.
- [12] Anttila, J. and Jussila, K., ISO 9001:2015 a questionable reform. What should the implementing organisations understand and do? Total Qual Manag Bus Excell., 28, pp. 1090-1105, 2017. DOI: 10.1080/14783363.2017.1309119.
- [13] Gotzamani, K.D., Tsiotras, G.D., Nicolaou, M., Nicolaides, A. and Hadjiadamou, V., The contribution to excellence of ISO 9001: the case of certified organisations in Cyprus. TQM Mag., 19, pp. 388-402, 2007. DOI: 10.1108/09544780710817838.
- [14] Chan, Y.K., Kam, J., Neailey, K. and Ip, W.H., How IMS can achieve ISO 9001:2000 certification. TQM Mag., 14, pp. 345-349, 2002. DOI: 10.1108/09544780210447447.
- [15] Du, Y., Yin, J. and Zhang, Y., How innovativeness and institution affect ISO 9000 adoption and its effectiveness: evidence from small and medium enterprises in China. Total Qual Manag Bus Excell., 27, pp. 1315-1331, 2016. DOI: 10.1080/14783363.2015.1075874.
- [16] Tarí, J.J., Components of successful total quality management. TQM Mag., 17, pp. 182-194, 2005. DOI: 10.1108/09544780510583245.
- [17] Martínez-Lorente, A.R. and Martínez-Costa. M., ISO 9000 and TQM: substitutes or complementaries? Int J Qual Reliab Manag., 21, pp. 260-276, 2004. DOI: 10.1108/02656710410522711.
- [18] Han, S.B., Chen, S.K. and Ebrahimpour, M., The impact of ISO 9000 on TQM and Business Performance. Jorunal Bus Econ Stuides;13, pp. 1-24, 2007.
- [19] Stanciu, I. and Pascu, E., Some aspects of adaptation ISO 9000 to TQM. Knowl Horizons – Econ. 6, pp. 31-34, 2014.
- [20] Escanciano, C. and Iglesias-Rodríguez, F.J., Quality management and integrated total quality in Spanish mining: results of an empirical study. DYNA, 79, pp. 167-174, 2012.
- [21] Oke, S.A. and Owaba-Charles, O.E., Implementation of ISO-based quality management systems: a review of the literature. Int J Product Qual Manag., 2, pp. 81-111, 2007. DOI: 10.1504/IJPOM.2007.011469.
- [22] International Organization for Standardization. ISO 9001 Quality Management Systems - Requirements. 2015.
- [23] Brotherton, B. and Shaw, J., Towards an identification and classification of critical success factors in UK Hotels Plc., Int J Hosp Manag., 15, pp. 113-135, 1996. DOI: 10.1016/0278-4319(96)00014-X.
- [24] Quazi, H.A. and Padibjo, S.R., A journey toward total quality management through ISO 9000 certification - a study on small- and medium-sized enterprises in Singapore. Int J Qual Reliab Manag., 15, pp. 489-508, 1998. DOI: 10.1108/02656719810196225.
- [25] Sun, H., Total quality management, ISO 9000 certification and performance improvement. Int J Qual Reliab Manag., 17, pp. 168-179, 2000. DOI: 10.1108/02656710010304573.

- [26] Soltani, E. and Lai, P.-C., Approaches to quality management in the UK: survey evidence and implications. Benchmarking An Int J; 14, pp. 429-54, 2007. DOI: 10.1108/14635770710761852.
- [27] International Organization for Standardization. Quality management principles, 2015. DOI: ISBN 978-92-67-10650-2.
- [28] Santos, G., Rebelo, M., Lopes, N., Alves, M.R. and Silva, R., Implementing and certifying ISO 14001 in Portugal: motives, difficulties and benefits after ISO 9001 certification. Total Qual Manag Bus Excell., 27, pp. 1211-1223, 2015. DOI: 10.1080/14783363.2015.1065176.
- [29] Taylor, W.A., Organizational differences in iso 9000 implementation practices. Int J Qual Reliab Manag., 12, pp. 10-27, 1995. DOI: 10.1108/02656719510093529.
- [30] Maza-Rubio, M.T. and Ramírez-Arias, V., Study of main motivations and discouraging factors for the implementation of ISO 9000 standards in Spanish agribusiness sector. J Int Food Agribus Mark., 17, pp. 229-243, 2005. DOI: 10.1300/J047v17n02.
- [31] Sampaio, P., Saraiva, P., Guimarães-Rodrigues, A., ISO 9001 certification research: questions, answers and approaches. Int J Qual Reliab Manag., 26, pp. 38-58, 2009. DOI: 10.1108/02656710910924161.
- [32] Ab-Wahid, R., Beyond certification: a proposed framework for ISO 9000 maintenance in service. TQM J., 24, pp. 556-568, 2012. DOI: 10.1108/17542731211270115.
- [33] Turner, C.R., Ortmann, G.F. and Lyne, M.C., Adoption of ISO 9000 quality assurance standards by South African agribusiness firms. Agribusiness., 16, pp. 295-307, 2000. DOI: 10.1002/1520-6297(200022)16:3<295::AID-AGR3>3.0.CO;2-P.
- [34] Capmany, C., Hooker, N.H., Ozuna, T. and Van Tilburg, A., ISO 9000 a marketing tool for U.S. agribusiness. Int Food Agribus Manag Rev., 3, pp. 41-53, 2000. DOI: 10.1016/S1096-7508(00)00027-6.
- [35] Gonzalez-Torre, P., Adenso-Diaz, B. and González, B.A., Empirical evidence about managerial issues of ISO certification. TQM Mag., 13, pp. 355-360, 2001. DOI: 10.1108/EUM000000005861.
- [36] Boiral, O., ISO 9000 and organizational effectiveness: a systematic review. Qual Manag J., 19, pp. 16-37, 2012.
- [37] Aggelogiannopoulos, D., Drosinos, E.H., Athanasopoulos, P., Implementation of a quality management system (QMS) according to the ISO 9000 family in a Greek small-sized winery: a case study. Food Control., 18, pp. 1077-1085, 2007. DOI: 10.1016/j.foodcont.2006.07.010.
- [38] Ab-Wahid, R. and Corner, J., Critical success factors and problems in ISO 9000 maintenance. Int J Qual Reliab Manag., 26, pp. 881-893, 2009. DOI: 10.1108/02656710910995073.
- [39] Psomas, E.L., Kafetzopoulos, D.P. and Fotopoulos, C.V., Developing and validating a measurement instrument of ISO 9001 effectiveness in food manufacturing SMEs. J Manuf Technol Manag., 24, pp. 52-77, 2013. DOI: 10.1108/17410381311287481.
- [40] Naser-Abdulrahman, A., Application of quality tools by Saudi food industry. TQM Mag., 19, pp. 150-61, 2007. DOI: 10.1108/MBE-09-2016-0047.
- [41] Kafetzopoulos, D.P. and Gotzamani, K.D., Critical factors, food quality management and organizational performance. Food Control., 40, pp. 1-11, 2014. DOI: 10.1016/j.foodcont.2013.11.029.
- [42] Singh, P.J. and Smith, A., An empirically validated quality management measurement instrument. Benchmarking An Int J., 13, pp. 493-522, 2006. DOI: 10.1108/14635770610676317.
- [43] Wilcock, A.E. and Boys, K.A., Improving quality management: ISO 9001 benefits for agrifood firms. J Agribus Dev Emerg Econ., 7, pp. 1-37, 2017. DOI: 10.1108/JADEE-10-2013-0040.
- [44] Magd. H. and Curry, A., ISO 9000 and TQM: are they complementary or contradictory to each other? TQM Mag., 15, pp. 244-256, 2003. DOI: 10.1108/09544780310486155.
- [45] Dowlatshahi, S., An empirical study of the ISO 9000 certification in global supply chain of maquiladoras. Int J Prod Res., 49, pp. 215-234, 2011. DOI: 10.1080/00207543.2010.508949.
- [46] ISO. The ISO Survey [online]. n.d. [accessed May 8, 2019]. Available at: https://www.iso.org/the-iso-survey.html
- [47] Instituto Nacional de Estadística y Geografía. Producto Interno Bruto. PIB. Trimestral. Cuentas Bienes y Serv del Sist Cuentas Nac México SCNM; Prod Interno Bruto Trimest. [en línea]. n.d. (accessed May 8,

- 2019]. Disponible en: http://www.beta.inegi.org.mx/temas/pib/ ().
- [48] Instituto Nacional de Estadística y Geografía. Directorio de empresas y establecimientos [en línea]. n.d. [accessed May 8, 2019]. Disponible en: https://www.inegi.org.mx/temas/directorio/
- [49] Secretaría de Economía. ISO 9000 [en línea]. n.d. [accessed May 8, 2019]. Disponible en: |http://www.economia-iso9000.gob.mx/normasIso9000/iso9000.do (accessed May 8, 2019).
- [50] Gomes-Salgado, E., Beijo, L.A., Sampaio, P., Pereira-Mello, C.H. and Saraiva, P., ISO 9001 certification in the American Continent: a statistical analysis and modelling. Int J Prod Res., 54, pp. 5416-5433, 2016
- [51] International Organization for Standardization/Technical Committee 176. What is ISO/Technical Committee (TC) 176, [online]. 2018. [accessed June 25, 2019]. Available at: https://committee.iso.org/home/tc176
- [52] Feng, M., Terziovski, M. and Samson, D., Relationship of ISO 9001:2000 quality system certification with operational and business performance: a survey in Australia and New Zealand-based manufacturing and service companies. J Manuf Technol Manag., 19, pp. 22-37, 2008. DOI: 10.1108/17410380810843435.
- [53] Dellana, S. and Kros, J., ISO 9001 and supply chain quality in the USA. Int J Product Perform Manag., 67, pp. 297-317, 2018. DOI: 10.1108/JJPPM-05-2015-0080.
- [54] Jasarevic, S., Diering, M., Hadzistevic, M. and Plevjkak, F., Influence of introduction time, size and activity of organization to the achieved efects of introduced quality system. Int J Eng., 10, pp. 21-30, 2012.
- [55] Stainslaus, R.L., Premaratne, S. and Tritos, L., Quality management capabilities of manufacturing industries in the Western Sydney region: comparative analysis for quality improvement. Int J Qual Reliab Manag., 35:1232-1252, 2018.
- [56] Almeida, D., Pradhan, N. and Muniz, J.J., Assessment of ISO 9001:2015 implementation factors based on AHP: case study in Brazilian automative sector. Int J Qual Reliab Manag., 34, pp. 231-250, 2018. DOI: 10.1108/02656710710748349.
- [57] Poksinska, B., Eklund, J.A.E., Jörn-Dahlgaard, J., ISO 9001:2000 in small organisations: lost opportunities, benefits and influencing factors. Int J Qual Reliab Manag., 23, pp. 490-512, 2006. DOI: 10.1108/02656710610664578.
- [58] Texeira-Quirós, J., Ferndandes Justino, M. do R., A comparative analysis between certified and non-certified companies through the quality management system. Int J Qual Reliab Manag., 30, pp. 958-969, 2013. DOI: 10.1108/IJORM-04-2011-0059.
- [59] Dowlatshahi, S. and Hooshangi, S., Enabling quality management systems in the maquiladoras: an empirical analysis. Int J Qual Reliab Manag., 27, pp. 981-1001, 2010. DOI: 10.1108/02656711011084792.
- [60] Murmura, F. and Bravi, L., Empirical evidence about ISO 9001 and ISO 9004 in Italian companies. TQM J;29, pp. 650-665, 2017. DOI: 10.1108/TQM-11-2016-0097.
- [61] Sfakianaki, E. and Kakouris, A.P., Obstacles to ISO 9001 certification in SMEs. Total Qual Manag Bus Excell., 0, pp. 1-21, 2018. DOI: 10.1080/14783363.2018.1490640.
- [62] Rogala, P., Identification of barriers to improving quality management systems. The management representatives' perspective. TQM J., 28, pp. 79-88, 2016. DOI: 10.1108/TQM-05-2014-0047.
- [63] Prodromos, C., Chatzoudes, D. and Kipraios, N., The impact of ISO 9000 certification on firms' financial performance. Int J Oper Prod Manag., 35, pp. 145-74, 2015. DOI: 10.1108/IJOPM-07-2012-0387.
- M. Sanchez-Lizarraga, received the BSc. Eng. in industrial engineering from Autonomous University of Occident, Sinaloa, Mexico in 2011 and the MSc. in industrial engineering from the Technological Institute of Los Mochis, Mexico in 2013. He is currently pursuing the PhD. in science with the Faculty of Engineering, Architecture and Design, Autonomous University of Baja California, Mexico. He is also a professor with the Academic Business Unit, Autonomous University of Sinaloa. His current research interest includes ISO 9001 critical success factors in manufacturing sector in Mexico.

ORCID: 0000-0001-8730-9913.

J. Limon-Romero received the BSc. Eng. in industrial engineering from the Technological Institute of Los Mochis, Mexico, in 2001, and the MSc. in

industrial engineering from the Technological Institute of Hermosillo and the Dr. of Science from the Autonomous University of Baja California, Mexico, in 2004 and 2013, respectively. He is currently a professor of industrial engineering with the Faculty of Engineering, Architecture and Design, Autonomous University of Baja California, Mexico. He is the author/coauthor of more than 30 journal articles, book chapters, and conference papers. His research focuses on processes and products optimization working with methodologies such as six sigma and lean manufacturing. He is a member of the National System of Researchers of the National Council of Science and Technology, Mexico, and a member of the optimization of industrial processes network (ROPRIN). ORCID: 0000-0003-2117-4803.

- **D. Tlapa**, received the BSc. Eng. in industrial engineering from the Technological Institute of Ciudad Juarez, Mexico, in 2002, and the MSc. in industrial engineering and the Dr. of Science from the Autonomous University of Baja California, Mexico, in 2007 and 2013, respectively. He is currently a professor of industrial engineering with the School of Engineering, Architecture and Design, Autonomous University of Baja California. He is the author/coauthor of more than 30 journal articles, book chapters, and conference papers. His researches focus on supply chain management, and processes improvement projects including six sigma and lean manufacturing. He is a member of the National System of Researchers of the National Council of Science and Technology, Mexico, and a member of the optimization of industrial processes network (ROPRIN). ORCID: 0000-0002-1491-5442
- Y. Baez-Lopez, received the BSc. Eng. in industrial engineering from the Technological Institute of Los Mochis, Mexico, in 2002, and the MSc. in industrial engineering and the Dr. of Science from the Autonomous University of Baja California, in 2008 and 2014, respectively. She is currently a professor of industrial engineering with the Faculty of Engineering, Architecture and Design, Autonomous University of Baja California. Her research interests include six sigma methodology, lean manufacturing, and human reliability. She is coordinating a project directed manufacturing companies in northern Mexico. Dr. Baez-Lopez is a member of the National System of Researches of the National Council of Science and Technology, Mexico.

ORCID: 0000-0001-8418-254X



UNIVERSIDAD NACIONAL DE COLOMBIA

SEDE MEDELLÍN FACULTAD DE MINAS

Área Curricular de Ingeniería Eléctrica e Ingeniería de Control

Oferta de Posgrados

Maestría en Ingeniería - Ingeniería Eléctrica Maestría en Ingeniería - Automatización industrial Especialización en Eco-eficiencia Industrial

Mayor información:

E-mail: ingelcontro_med@unal.edu.co Teléfono: (57-4) 425 52 64