Chapter 12
Enablers and Barriers for a Quality Management System Implementation in Mexico: An Exploratory Analysis

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Abstract Organizations need to find the best practices in their operations to develop products or services that meet customer specifications; therefore, implementing a quality management system such as the ISO 9001 standard could provide these organizations with a framework to develop the continuous improvement of their work systems to meet or even exceed customer requirements while accomplishing the organization objectives. This chapter presents the ISO 9001 standard and the analysis performed to identify the critical success factors (CSFs) that enable its implementation based on a surveying instrument previously designed taking as reference the seven quality management principles (QMPs) stated by the ISO 9001:2015. To identify these enablers, an exploratory factor analysis (EFA) was carried out based on information collected from organizations in the manufacturing sector in Mexico. Results showed that engagement of people, customer satisfaction and decision making as well as leadership are the main factors that integrate the QMPs to facilitate the adoption of the standard in the manufacturing sector. Furthermore, the main barriers and the benefits related to the implementation of the standard are presented and discussed.

Keywords Critical success factors · ISO 9001 standard · Manufacturing sector quality management system · Survey

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12.1 Introduction

The fulfillment of the characteristics that provide quality to the products or services is one of the main features that organizations pursuit into a level that satisfies the customer's needs and requirements. To accomplish these features, a quality management system (QMS) has been a strategy implemented by many organizations to meet them, and at the same time achieve customer satisfaction. Hallberg et al. (2018) conceptualize the QMS as systems certified to ensure that the company has processes in place for various routines and theorize that the QMS could delimit the selection of qualified suppliers, thereby demonstrating an upstream pressure for such QMS applied. Also, Garza-Reyes et al. (2015) described that the use of a QMS is essential to support the performance of organizations, provides a range of benefits for improvement, and therefore, positively affects the organization. Likewise, Gargasas et al. (2019) describe that QMS involves aspects such as occupational safety and environmental protection, focus on customer and employee health and observance of the needs of society. Finally, Bravi et al. (2019) state that quality is a philosophical perspective; therefore, the implementation of a QMS and its subsequent certification is a voluntary process, supported by the motivations, objectives and policies of the organization.

Many QMS are related to quality methodologies and strategies such the Malcolm Baldrige National Quality Award (MBNQA), European Foundation for Quality Management (EFQM), Six Sigma (SS), Total Quality Management (TQM), Lean Manufacturing (LM) and the ISO 9001 standard among others. In this chapter, the ISO 9001 standard is the main focus to describe it as a QMS. The chapter will be divided into six main topics: (1) history, revisions, definition and structure of the standard; (2) the ISO 9001 standard framework; (3) the critical success factor for its implementation; (4) a development of a measurement instrument to recognize the critical success factors in the implementation in the manufacturing sector in Mexico; (5) discussion; and (6) conclusion.

12.1.1 A Brief History of the International Standardization Organization and ISO 9001 Standard

The International Organization for Standardization (ISO) was created from the union of two organizations—one was the ISA (International Federation of the National Standardizing Associations), established in New York in 1926, and administered from Switzerland, and the other was the United Nations Standards Coordinating Committee (UNSCC), established in 1944, and administered in London. The conference of national standardizing organizations which established the ISO took place in London 1946. The ISO is an independent, non-governmental international organization established in Geneva, Switzerland, with a membership of 164 national standards bodies (ISO 1997). The ISO is a network of national standards bodies

(NSB) which each member represents ISO in its country. ISO standards are developed by groups of experts which form technical committees (TC). Each TC deals with a different subject and is made up of representatives of industry, non-governmental organizations (NGOs), governments and other stakeholders, who are put forward by ISO's members (Hoyle 2018). But ISO is much more; it is the key component in a worldwide standardization system, and it is accepted as such, because it respects the competence and autonomy of all the other elements of the system, while being careful to keep in view the necessary synergies and compatibilities (ISO 1997).

For many years, ISO was participating in discussions dealing with testing a quality control, but not until 1978 the ISO start its own program by "Spike" Spickernell, Director General of the British Standards Institution, and stimulated a lot of discussion before the title and scope for a new technical committee were agreed upon. The result was a Technical Committee 176 (TC 176) for quality management and quality assurance which would eventually produce one of most spectacular standards: the ISO 9000 series (ISO 1997). The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards providing guidance and tools for organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved (ISO 2015).

The ISO Survey of Certifications is an annual survey of the number of valid certificates to ISO management system standards worldwide such as ISO 9001 and ISO 14001. The latest results of the survey are from 2018 which show an estimation of the number of valid certificates. According to the ISO Survey (2018), the popularity of the ISO 9001 standard can be measured with the number of organizations adopting the standard worldwide; the first 10 countries with more certified organizations are listed in Table 12.1, where China, Germany, Japan, Italy and UK and Northern Ireland are the top five countries with the most certified organizations.

Likewise, the ISO Survey (2017) shows the total number of organizations certified worldwide. Figure 12.1 shows noticeable variability in the worldwide growth from year 2007 to 2017 of the ISO 9001 standard, where year 2016 presents the highest number of certifications obtained with 1,105,937 organizations certified; this could have happened due to the transition from the ISO 9001:2008 to 9001:2015 in organizations. After almost 25 years and many versions, the expectation caused by the ISO 9001 standard endorses the standard as a reference for organizations that wish to implement an efficient and effective QMS.

12.2 The ISO 9001 Standard

The management of the standard in Mexico comes directly from the General Direction of Standardization (DGN, for its acronym in Spanish) that is an internal institution of the Economic Ministry responsible to arrange the Mexican Norms (NOM, for its acronym in Spanish) to coordinate the standardization and conformity assessment systems to promote the competitiveness of industry and commerce in the national

Table 12.1 Countries with the highest number of certified organizations with ISO 9001:2015 standard

Rank	Country	Total
1	China	160587
2	Germany	30312
3	Japan	29398
4	Italy	22982
5	UK of Great Britain and Northern Ireland	17433
7	India	15974
8	Spain	12992
9	USA	11047
10	France	7704
11	Australia	6101
12	Czech Republic	5953
13	Brazil	5591
14	Thailand	5192
15	Switzerland	5075
16	Israel	4453
17	Netherlands	4451
18	Taiwan, Province of China	4444
19	Korea (Republic of)	4360
20	Malaysia	4283
21	Poland	3794
22	Argentina	3560
23	Indonesia	3075
24	Hungary	3059
25	Portugal	2974
26	Bulgaria	2832
27	Canada	2641
28	Colombia	2603
29	Mexico	2577
30	Romania	2545

Source ISO survey (2018)

and international scope. The DGN with The Mexican Institute of Standardization and quality assurance standard 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 stablished by the ISO. Finally, the Mexican Accreditation Body (EMA, for its acronym in Spanish) is a private institution with governmental permission to be responsible for the accreditation of the Conformity Assessment Bodies to evaluate and certificated the organizations once accomplishing the requirements for the ISO 9001 standard/NMX-CC-9001-2015.

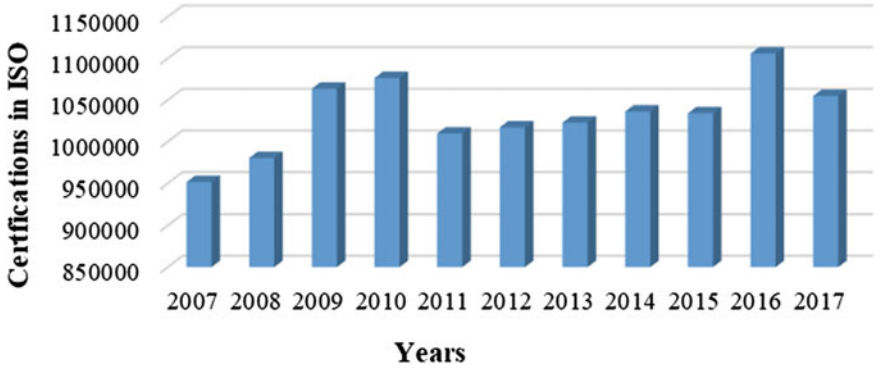

Fig. 12.1 Organizations with ISO 9001 certification worldwide over time. *Source* ISO survey (2017)

12.2.1 History and Follow up of the ISO 9001 Standard

12.2.1.1 ISO 9001:1987

Although the ISO 9000:1987 is not recognized as the first edition of the standard, it was the first to include the guidelines, requirements and terminology of a QMS mainly based on BS-5750 series from the British Ministry of Defense (Harrigan 1993; Lopez 2016; Wilson and Campbell 2016). The emphasis of the application of the ISO 9000 series on this version was between customers and suppliers, taking into account that the BS-5750 was emphasized between governments and manufactures (Lopez 2016). The series embraces the following standard in its structure:

- ISO 8402:1986 Quality—Vocabulary.
- ISO 9000. Quality Management and Quality Assurance Standard—Guidelines for Selection and Use.
- ISO 9000-2. Quality Management and Quality Assurance Standards—Part 2: Generic Guidelines for the Application of ISO 9001, ISO 9002 and ISO 9003.
- ISO 9000-3. Quality Management and Quality Assurance Standards—Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software.
- ISO 9001. Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation and Servicing.
- ISO 9002. Quality Systems—Model for Quality Assurance on Production, Installation and Servicing.
- ISO 9003. Quality System—Model for Quality Assurance in Final Inspection and Test.
- ISO 9004:1987. Quality Management and Quality System Elements—Guidelines.
- ISO 10011-1. Guidelines for Auditing Quality Systems—Part 1: Auditing.

- ISO 10011-1. Guidelines for Auditing Quality Systems—Part 2: Qualification criteria for quality systems auditors.

12.2.1.2 ISO 9001:1994

ISO 9001:1994 standard emphasized quality assurance via preventive actions, instead of just checking the final product and continued to require evidence of compliance with documented procedures. As with the first version, the disadvantage was that companies tended to implement its requirements by creating shelf-loads of procedure manuals, and becoming burdened with an ISO bureaucracy (Wolniak 2018); however, at this time, the success of the standard was unstoppable in many countries. Also, the ISO 9001 standard became known as "reference standard" for other certifiable management standards such as the ISO 14001 (for environmental management) or OHSAS 18001 (for occupational safety and health management) among others (Lopez 2016). In 1997, ISO carried out a survey to more than thousand users of the standard to know their opinions and recollect proposals for the improvement of the ISO 9001:2000 standard. The ISO 9001:1994 contained following standards:

- ISO 8402:1994 Quality management and quality assurance—Vocabulary.
- ISO 9001:1994 Quality systems—Model for quality assurance in design, development, production, installation and servicing.
- ISO 9002:1994. Quality systems—Model for quality assurance in production, installation and servicing.
- ISO 9003:1994. Quality systems—Model for quality assurance in final inspection and test.
- ISO 9004-1:1994 Quality management and quality system elements—Part 1: Guidelines.
- ISO 9004-2:1994. Quality management and quality system elements—Part 2: Guidelines for services.
- ISO 9004-3:1993 Quality management and quality system elements—Part 3: Guidelines for processed materials.
- ISO 9004-4:1993 Quality management and quality system elements—Part 4: Guidelines for quality improvement.

12.2.1.3 ISO 9001:2000

In this version, many of the standards in the ISO 9000 series were discontinued in the publication of the new edition of the basic standards. The original 9002 and 9003 standards were merged with ISO 9001, and ISO 8402 was merged and designated as ISO 9000. The standards ISO 9004-1, 9004-2 and ISO 9004-3 merged and designated only as ISO 9004. ISO 10011 on auditing were merged with auditing standards for environmental management designated as ISO 19011 (Wolniak 2018). Another of the most important novelties of this edition is the adoption of the eight quality management principles (QMPs) that continue as a frame of reference for

the requirements of the standard and in the unquestionable pillars of any QMS. Figure 12.2 shows the eight quality principles established by the ISO in the ISO 9000:2000 series (ISO 2000). Other novel change in the standard was the process approach applied to develop structural processes using the PDCA cycle created by Deming relating all areas of the organization, since the identification of processes is a requirement of the standard.

Minor changes in this version were to simplify documentary load, simplify the contents to be more understandable, amplify the standard approach to apply to services companies and in the organization management, include the prevention approach in the problem correction and include the continuous improvement approach (Lopez 2016). With the changes described, it can be seen that the standard experienced a remarkable transformation in the aspect of quality management, not only in fulfilling the client's requirements, but also in integrating audit functions to the

Fig. 12.2 Eight quality management principles in the ISO 9001:2000 standard

organization's management to continuously improve the QMS. The ISO 9001:2000 contained the following standards:

- ISO 9000:2000. Quality Management Systems—Fundamentals and Vocabulary
- ISO 9001:2000. Quality Management Systems—Requirements
- ISO 9004:2000. Quality Management Systems—Guidelines for Performance Improvements
- ISO 19011: Guidelines for Auditing Management Systems

12.2.1.4 ISO 9001:2008

The survey for the improvement of the standard did not provide great changes needed for the 2008 revision. Changes were mainly made in the redaction of some requirements, just some descriptive notes and modifications in the text for a greater clarity. Consequently, transition from the ISO 9001:2000 to the 2008 version was simple to carry out because no structural changes were necessary either in the requirements of the quality management.

12.2.1.5 ISO 9001:2015

The draft of the new version of the standard started with the compilation of the improvement needs given by expert and certification entities. The ISO 9001:2015 was finally recognized as an international standard in September 2015. Some strategic goals on which the TC 176 based its work for the improvement of the standard were:

- **Clarity in manual writing**: Without losing sight of the importance of the description of the requirements, there is a clear effort to simplify and clarify the wording.
- **Applicability of the standard**: The purpose is that the standard is applicable to all type of companies. The content of some requirements has been made more flexible, and also, the concept of exclusion disappears but is replaced by non-applicability.
- **Process approach**: Even though the process approach comes from the ISO 9001:2000 standard, this version is reinforced and distinct in the QMS determining a right management of the processes.
- **Risk based thinking**: This approach reinforces the preventive nature of the QMS that was implicitly in the previous versions of the standard. Now preventive actions are eliminated and replaced by a more effective tool such as risk analysis. The ISO 9001:2015 does not include any requirement about the risk management methodology used by the organization.
- **Flexibility in documentation**: This version of the standard focus in the elimination of the conceptual documentation, procedure, instruction or register and its replacement with the term "documented information." Also, the obligation to

Table 12.2 Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used
Management representative	Not used (similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedure, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

Source (ISO 2015)

maintain certain documentation such as the manual of quality or the old documented procedures manual disappears, leaving to the organization the criterion on the type and size of its documentary system.

In the ISO 9001:2015, quality management requirements manually displays a differentiation matrix against ISO 9001:2008 that can be shown in Table 12.2.

12.2.2 Standardization Process of ISO 9001 Standard

All ISO standards are reviewed by their TC every five years in order to analyze if the standard needs any modification or update to maintain its validity and relevance; in this case, the TC 176 is responsible for carrying out this activity (Lopez 2016). The revision for the standardization process of the ISO 9001 standard is divided into six phases according to Lopez (2016) and Hoyle (2018):

1. *Systematic review (NWIP)*: In the New Work Item Proposal (NWIP) phase, the TC performs the evaluation of the standard to determine if it requires a change or modification in any of the requirements. The TC considers the recommendations, observations and proposals from all the participants involved in the development of the standard such as organizations and certification houses.
2. *Design specification (WD)*: With the proposed content accepted, the expert group begins a discussion to prepare a working draft (WD). Each section of the draft usually is commissioned to a specific group or subcommittees (SC) including opinions of experts from around the world of recognized prestige.
3. *Committee draft (CD)*: The WD is shared with the TC and with ISO CS (Central Secretariat), the TC comment and vote about the content of every draft made

until reaching a concession, then a final committee draft (CD) is made and distributed to the TC as an internal draft.

4. *Draft international standard (DIS)*: The final CD is submitted to vote by the TC to be registered as a Draft International Standard (DIS). The DIS is shared with all ISO national members, who have three months to comment. The TC as well the SC should notice all comment from the members of the ISO and review the DIS; when this happens, another review period of a new CD is established.
5. *Final projects of international standard (FDIS)*: In this approval stage, the Final Draft of the International Standard (FDIS) is review again for the ISO national members for two months for analysis and vote. The standard is approved by a two-thirds majority of the participation members which is in favor and not more than one-quarter of the total votes are negative. Only editorial corrections are made to the final text.
6. *International Standard*: Once the FDIS is accepted, its technical content cannot be modified and finally is published as an ISO international standard.

12.2.3 The ISO 9001:2015 Standard

One of the most recognized and implemented QMS worldwide is the ISO 9001 standard to facilitate international and national recognition of quality requirements in organizations (Salagean et al. 2014). This standard helps organizations to satisfy customers, meet regulatory requirements and achieve continuous improvement regardless the size or activity of the organization (ISO 2015); hence, the ISO 9001 standard disposes the guidelines to improve the quality system in the company. The most recent version of the standard is the ISO 9001:2015 that emphasizes the adequate management of activities to accomplish and exceed the customer requirements (Wecjenmann et al. 2015); in others words, organizations use the ISO 9001 standard to demonstrate to customers their capability and performance within its working systems to offer the confidence of satisfy their needs and expectations while committing to continuous improvement.

The ISO 9001:2015 standard uses three principal scopes for its functionality: the process approach which incorporates the PDCA cycle (Plan-Do-Check-Act) enabling an industry to plan its process related with its resources and internals interactions; risk-based thinking that enables an industry to find circumstances that could cause troubles and malfunctions in its QMS placing preventive controls to minimize negative effects and make the maximum usage of opportunities as they occur (Manders et al. 2016); and the seven quality management principles (Fig. 12.3) (Farinha et al. 2016; Manders et al. 2016). Likewise, Heuvel (2007) and Kutnjak et al. (2019) detail how the standard takes the process approach to improve organizational and financial performance with a specific focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory performance or non-conformance. Also, Kutnjak et al. (2019) affirm that quality in business operations models by the ISO 9001 standard is one of the ways of improving

Fig. 12.3 Seven quality management principles in ISO 9001:2015 standard

competitiveness in the entire benchmark or industry sector. None of the guidelines of the standard contain requirements with which a product or service can comply, and there are no product acceptance criteria in the ISO 9000 series; in this wise, the standard cannot inspect a product against the standard terms and guidelines, providing that the main interest of the ISO 9001 standard is only the QMS of the business (Salagean et al. 2014).

As described above, it is recognized that the ISO 9001:2015 standard provides theoretical and practical knowledge for the development of a system that manages the quality of an organizations based on rising awareness of all work areas into the continuous improvement of processes and activities performed to the fulfillment of the requirements and needs of customers. The greatest value obtained of the standard is by using the entire set of standards in an integrated manner; it is highly recommended that an organization using the ISO 9001 standard become acquainted

with the fundamental concepts, principles and normative vocabulary of a QMS before adoption of the standard to achieve an effective level of performance (ISO 2016).

12.2.3.1 High-Level Structure in Management System Standards of the ISO

The ISO has published many standards in almost all important topics by the industry or government, and the management system standards of the ISO (MSS) are among the most widely used and recognized documents such as ISO 9001, ISO 14001 and ISO 50001. In an organization, especially the big companies have five or six certifications in quality management, environmental management, logistics, safety, information safety management or energy management to mention a few. Aware of the problem of integrating the different management standards and avoiding as far as possible duplications and inconsistencies between the systems, the Joint Technical Coordination Group (JTCG) of the ISO developed a structure of a "generic" management system to guarantee the compatibility with other systems. The concept of a high-level structure (HLS) is that management standards are structured in the same way, regardless of the domain of application. Users who are familiar with one MSS will immediately feel ease with another, even when using if for the first time, in other words, the standard with a HLS has the same structure and contains many of the same terms and definitions. The basic requirements for a HLS are: (1) equal number of chapters; (2) equal introductory text for all manuals; (3) identical statements for identical requirements and; (4) common terms. The HLS can be found as SL annex in every requirement standard manual to play a key role in the interoperability and user friendliness of standards for countless users of ISO management standards (Lopez 2016).

The HLS has been applied in some quality management systems standards that can be consulted at the ISO webpage: https://www.iso.org/management-system-standards-list.html.

12.2.3.2 High-Level Structure in the ISO 9001:2015

The HLS of the ISO 9001:2015 standard consists of ten closures or chapters. The first three closures describe generalities of the standard: where can be implemented, what normative can be referenced and the main terms and definitions to understand the standard and, from closure 4 to 10 the requirements of the QMS are defined. So, to exemplify what is the HLS in the ISO 9001:2015 is the arrangement of how standard is written and structured in the requirement manual. Table 12.3 shows the closures and its name.

Table 12.3 HLS of the ISO 9001:2015 standard

Closure number	Name
Closure 1	Scope
Closure 2	Normative references
Closure 3	Terms and definitions
Closure 4	Context of the organization
Closure 5	Leadership
Closure 6	Planning
Closure 7	Support
Closure 8	Operation
Closure 9	Performance evaluation
Closure 10	Improvement

Source ISO 9001:2015 quality management system—Requirements

12.2.4 Structural Standards of the ISO 9000 Family

The international quality management ISO 9000 series standards has earned a global status as a basis for establishing effective and efficient QMS. The need for international standards makes more organizations operate in the global economy by selling or buying products and services from sources outside their domestic surroundings. According to the quality management system requirement manual of the ISO 9001:2015, the standard is a set of almost 20 complementary standards that provide the theoretical and practical support to organizations; however, in this section only five of them will be described as main core standards because they describe and define all the basics and methodologic procedures to its adaptability in an organization.

1. *ISO 9000:2015 Quality management system—Fundamentals and vocabulary*: This standard describes the fundamental concepts of quality management which are universally applicable to organizations seeking sustained success through the implementation of a QMS. The ISO 9000 provides concepts and vocabulary used in the entire ISO 9000 series as well the introduction of with the seven QMPs and the use of the process approach to achieve continual improvement.
2. *ISO 9001:2015 Quality management system—Requirements*: This standard specifies the requirements against which QMS can be certified by an external body. The ISO 9001 recognizes that the term "products and services" applies to services, processed material, hardware and software intended for customer. The requirements in all sections of ISO 9001 are applicable. Organizations will need to provide justification for any requirement of this standard that the organization determines is not applicable to the scope of its QMS.
3. *ISO 9004:2018 Management for the sustained success of an organization*: the ISO 9004:2018 gives guidance on a wider range of objectives of a QMS than ISO

9001; in other words, the ISO 9004 manages the long-term success of an organization. The ISO 9004 is designed to serve as a guide for QMS implementation, maintenance and enhancement in any type of organization and is clearly oriented toward directing top management to accept responsibility for QMS performance improvement. Likewise, Jarvis and Palmes (2018), define the standards as an encouragement to go beyond the fundamental QMS requirements to extend the benefits of the ISO 9001 in pursuit of systematic and continual improvement of the performance of an organization; however, the standard is not intended for certification or contractual purposes.

4. *ISO 10001:2018 Quality management—Customer satisfaction—Guidelines for code of conduct for organizations*: This standard provides guidance for planning, designing, developing, implementing, maintaining and improving customer satisfaction codes of conduct. Mohammad et al. (2015) describe how the term "code" is used by the standard as a promises made to customers by an organization concerning its behavior that are aimed at enhanced customer satisfaction, the code of the standard is consistent with the term service guarantee.
5. *ISO 19011:2018—Guide for systems audit administration*: this standard covers the area of auditing the QMS and environmental management systems. Sukoco et al. (2012) describe that the ISO 19011 emphasizes the importance of audits as a management tool for monitoring and verifying the effective implementation quality policy. This standard provides an overview of how an audit should operate. Effective audits ensure the QMS implementation meeting the requirements specified in ISO 9001 standard.

12.2.5 Quality Standards Based on the ISO 9001 Standard

Although the ISO 9001 standard is described as the most recognized certification in the world covering all functional areas by standardizing production processes to meet customer requirements, there are productive sectors where processes need a higher degree of demand to meet quality and production requirement that the ISO 9001 standard does not emphasize. That is why standards have been created based on ISO 9001 to meet requirements to these sectors cover the needs in their products or services with a greater exigency to accomplish the quality requirements. Each standard is listed below, and Table 12.4 shows the ISO Survey (2018) results as well the amount of certified organizations and its variability against years. It should be noted that, although AS 9100 and ISO/TC 16949 are not propriety of ISO, these standards are created based on the ISO 9001 standard. For further information about each standard, the ISO webpage can be consulted.

- ISO 13485:2016 quality management in medical products
- ISO 14001:2015 environmental management system—requirements with guidance for use
- ISO 18091:2019 quality management to apply ISO 9001 in government
- ISO 22000:2018 food quality management

Table 12.4 Organizations certified with standards based on ISO 9001 standard worldwide

Standard	Year		Variation (%)
	2017	2018	
ISO 9001:2015	758,344	739,206	−3
ISO 13485:2003 and 2016	15,840	14,618	−8
ISO 14001:2015	251,343	258,566	3
ISO 22000:2005 and 2018	26,652	27,091	2
ISO IEC 27001:2013	15,848	16,523	4
ISO 50001:2011	13,827	14,549	5

- ISO/IEC 27001:2013 information technology—security techniques—information security management systems—requirements
- ISO/TS 29001:2010 quality management for oil, petrochemical and natural gas companies
- ISO 50001:2018 energy management system—requirements with guidance for use
- AS 9100:2004 quality management system—requirements for aviation, space and defense organizations
- ISO/TS 16949:2009 quality management: requirements to apply ISO 9001:2008 in the automotive sector.

12.3 Critical Success Factors for ISO 9001 Standard Implementation

In the search for an adequate implementation of a QMS in work processes and systems, organizations are continuously searching which factors are important or are determined as critical for a successful implementation of QMS, these factors in literature are conceptualized as critical success factors (CSFs). According to Rockart (1979) cited by Kumar et al. (2009), defines the CSFs as factors for an organization to achieve success, that is, if these factors are not taken into account as essential, completed or fulfilled in the development of a project or activity, the failure of the organization is highly probable. Likewise, Brotherton and Shaw (1996) consider that the CSFs can be defined as the essential components that the organization needs to fulfill in order to obtain the greatest advantages and competencies to be able to achieve the proper implementation of a QMS; in this manner, the CSFs are the characteristics or elements that organizations need to develop and fulfill to a degree that the implementation of the QMS is satisfactory in all the processes and systems of the organization (Garza-Reyes et al. 2015). Even for Banuelas Coronado and Antony (2002); Jeyaraman and Kee Teo (2010) and Lande et al. (2016), the CSFs are the components that the organization targets to identify and develop in its processes to recognize which areas of the organization will produce the greatest competitive advantages. A vast amount of literature was consulted to find the CSFs that enable

organizations to implement a QMS based on the ISO 9001 standard (Quazi and Padibjo 1998; Sun 2000; Tarí 2005; Aggelogiannopoulos et al. 2007; Soltani and Lai 2007; Gotzamani et al. 2007; Dowlatshahi and Hooshangi 2010; Psomas et al. 2010; Sıtkı İlkay and Aslan 2012; Sumaedi and Yarmen 2015; Ismyrlis et al. 2015; Wilson and Campbell 2016; Farinha et al. 2016; Militaru and Zanfir 2016; Anttila and Jussila 2017a, b) remark different essential factors that allow the implementation of the ISO 9001 standard in organizations; however, the CSFs considered by them essentially agree with the QMPs presented in the ISO 9001:2015 standard; consequently, it is possible to recognize the QMPs as CSFs define them as the necessary characteristics that must be met by an organization for the adequacy and implementation of the standard. The QMPs and the corresponding definitions of the new version are shown in Table 12.5.

Table 12.5 QMPs in ISO 9001:2015 standard

Quality management principle	Definition
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)	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 such suppliers

Source ISO 9001:2015 Quality Management—Requirements and Farinha et al. (2016)

12.4 The ISO 9001 Standard Implementation in Mexican Companies

12.4.1 Methodology

The target population for the study involved all the companies within the manufacturing sector in Mexico (MSM) that have or have had the ISO 9001 standard certified preferably in the 2008 and 2015 versions within the SMEs and large company classification. A survey was developed for the needed data based on literature with 55 items in a five-point Likert scale (1: never, 2: rarely, 3: regularly, 4: almost always, 5: always) related to the level of use of each QMP. This survey was divided into four main sections: the first section with ten items for demographic data; the second correspond to the items for the QMPs (seven items for LD, four items for CF, six items for EP and PA and five items for IMP, EDM and RM); the third section with seven items related to benefits; and the last section with seven items associated with barriers. The survey could be answered by any personnel related to the quality system of the organization.

Over a period of two years, a total of 531 responses were obtained; however, only 183 responses were complete and usable for this study representing the 34.46% of the sample obtained. The software SPSS was used to perform the exploratory factor analysis (EFA). Factor Analysis (FA) is an interdependence technique whose main objective is to define the underlying structure between the variables in the analysis (Hair et al. 2009). In this research, the EFA is used to identify the structure of the measurement instrument and identify the potential factors that could emerge grouping items that are correlated and poses certain information in common. To identifying if FA is applicable to the database, the Bartlett's test of sphericity and the Kaiser–Mayer–Olkin (KMO) will be performed. The Bartlett's test of sphericity tests the null hypothesis that the correlation matrix of the variables is equal to the identity matrix and the Kaiser–Mayer–Olkin test is used to verify the correlation among the variables, KMO values greater than 0.7 are considered regular, values above 0.8 are great, and values beyond 0.9 are very good (Kaiser and Rice 1974), that is, if the KMO test results in a small number or very close to zero, the sample cannot be used for a FA (Hair et al. 2009). Finally, results corresponding to barriers and benefits related to the adoption of the standard are described in the discussion.

12.4.2 Results

12.4.2.1 Benefits of the ISO 9001 Standard Implementation

Many benefits can be acquired implementing the ISO 9001 standard in all types of business or industry; the benefits are related to the effective implementation of

the standard, for example, Gonzalez et al. (2001) reported a decrease in manufacturing times reducing waste which means, an increase improvement of the quality system. Some benefits by the ISO 9001 standard are related to the improvement of the manufacturing systems which leads to produce quality products, as the productivity and profit of the organization increase (Turner et al. 2000; Aggelogiannopoulos et al. 2007; Boiral 2012). Also, Psomas et al. (2013) defined how food enterprises can achieve some benefits with the standard such as continuous improvement, prevention of non-conformities and customer satisfaction focus with its implementation. Likewise, Anttila and Jussila (2017b) and Wilcock and Boys (2017) described that, when the industries increase productivity, the customer complaints tend to minimize; as a result, more customer satisfaction is achieved. According to the results obtained in the exploratory analysis, among the most reported benefits is the increase to customer satisfaction, the reductions of errors or defects, the integration of the continuous improvement culture and the decrease of waste and activities that do not add value to products.

12.4.2.2 Barriers for the ISO 9001 Standard Implementation

Sometimes the implementation of the ISO 9001 standard is not always as simple as it could be in the organizations, certain difficulties or barriers make the implementation impossible, in other words, barriers can be associated with various aspects such as the lack of focus on the CSFs for an adequate implementation (Santos et al. 2015). There are two common classifications for barriers: the ones related with leadership and the others related to the engagement of people. Barriers related to engagement of people creates problems such as: lack of people cooperation and involvement, lack of discipline following work methods, resistance to change, insufficient training and lack of motivation to improve (Turner et al. 2000; Ab Wahid 2012).

Destitute leadership carries problems such as misunderstanding ISO requirements, lack of communication, financial issues, lack of strategic thinking, poor audit systems, stationary issues and lack on continuous improvement focus (Taylor 1995; Maza and Ramírez 2005; Sampaio et al. 2009). Also, the large time of implementation to develop this kind of projects or limited resources for a short amount of time can be conceptualized as a barrier (Capmany et al. 2000; Turner et al. 2000). In relation to the results of the main barriers in the MSM, the most mentioned were the lack of the demand for the standard by the customers, followed by the high investment it requires. Also, organizations reported that its current QMS is better than the standard; hence, the standard becomes unnecessary. Finally, the bureaucratic paper work that the standard demands is another barrier reported.

12.4.2.3 Exploratory Factor Analysis and Enablers Definition

The Bartlett's test of sphericity was tested obtaining a chi-square approximation of 2259.23 with 153 degrees of freedom and a P-value = 0.00; therefore, the null

hypothesis cannot be accepted indicating that the correlation matrix is different from the identity matrix. Likewise, from the Kaiser–Mayer–Olkin test resulted a value of 0.949 which denotes that the sample is suitable for a FA. Finally, once that the evaluation of the database was suitable to factorize, the EFA was performed using the SPSS software and the principal components extraction method and Varimax rotation which are broadly reported in the literature (Psomas and Pantouvakis 2015; Xiong et al. 2016; Young et al. 2017; Macias-Velasquez et al. 2019). Table 12.6 shows the results obtained through the EFA.

Results of the EFA identified 18 variables related to the QMPs with a significant loading in three different factors, emerging this way the enablers. These loadings are greater than .4 considered for determining the influence of the item on the factor relative to the sample size (Hair et al. 2009). The grouping of the variables is notably structured by their own approach. For example, the items belonging to EP and IMP load in the same factor; therefore, it should be considered as one factor named *Engagement of People and Improvement (EPI).* In the same sense, the items from PA, CF, RM and EDM load together; hence, by the approach that this QMPs have in the standard, this factor could be named *Customer Satisfaction and Decision Making*

Table 12.6 Results of the EFA

Items	Factor			Eigenvalues	Cronbach's alpha
	EPI	CSDM	LID		
EP3	0.775			10.272	0.887
EP4	0.764				
EP1	0.753				
EP6	0.734				
EP2	0.725				
IMP4	0.684				
PA6		0.776		1.193	0.921
CF3		0.682			
RM2		0.659			
PA1		0.649			
EDM2		0.638			
PA4		0.623			
EDM4		0.620			
RM1		0.617			
LD2			0.839	1.010	0.902
LD4			0.694		
LD7			0.685		
LD3			0.657		
% Variance	24.536	18.582	26.192		
% Total variance	24.53	43.11	69.31		

(CSDM). Finally, the items related to LD loaded together on the same factor and because of this, and the original name of *Leadership (LD)* remained. Besides, from this table the corresponding Cronbach's alpha values for each one factor identified are shown. Values in the Alpha of Cronbach between .80 and 1.0 demonstrate an acceptable reliability and consistency (Cronbach 1951) which, in this case, the alpha values are within the values recommended. Finally, taking into account the three constructs obtained, the total variance explained is 69.31% which means that more than a half of the total phenomenon can be explain by the selected factors.

12.5 Discussion

The results of the EFA reveal that three main factors that integrate the seven QMPs that enable the implementation of the ISO 9001 standard in the MSM. Regarding EPI, CSDM and LD, similar factors have been reported in the literature. For example, Poksinska et al. (2006) describe how the top management leadership and the engagement of people provide the implementation of the standard. Also, Psomas et al. (2013) Manders et al. (2016); Almeida et al. (2018) and Stainslaus et al. (2018) describe the leadership as one of the main characteristics to arrange a QMS into the work procedures developing the organization goals and objectives. The customer focus, human resources management and the strategic planning of the quality should have the highest consideration when implementing the standard in an organization (Texeira and Fernandez 2013).

Finally, Xiong et al. (2016) and Dowlatshahi and Hooshangi (2010) reveal that the organizations certified in the ISO 9001 standard have an excellent relationship management, and with engaged personnel, a significant approach is accomplishing to fulfill the standard guidelines. The loading structure of the QMPs took place in the EFA made possible its classification into three factors; thus, it can be concluded that the EPI, CSDM and LID can be considered as the essential elements that need to be develop and accomplish for an adequate integration of the ISO 9001 standard in the manufacturing sector in Mexico.

According to the benefits reported in the EFA, these are similar to the benefits reported by Turner et al. (2000), Ahmad et al. (2006), Boiral (2012) and Psomas et al. (2013) describing how the implementation of the standard increases customer satisfaction and productivity. Likewise, Gonzalez et al. (2001) and Magd and Curry (2003) report that the implementation of the ISO 9001 integrates a continuous improvement approach increasing the productivity into the work systems, and as consequence, errors and waste are reduced increasing profit which resembles with the benefits reported in the MSM. In the matter of barriers, Prodromos et al. (2015) mention how the lack of commitment by the top management and financial or resources limitation hinders the assessment of the standard. Moreover, Rogala (2016) and Bravi and Murmura (2017) mentioned that the bureaucracy of the standard into de process, the lack of interest of the management, the high investment and the long time required for its implementation are obstacles and limitations. According to the EFA, the high

investment and the bureaucracy agree with the results obtained; however, the main barrier reported in the MSM is the lack of demand of the standard by the customers unlike the literature consulted where this is not reported as a barrier.

12.6 Conclusions

Currently, organizations seek to find the best practices to manage the activities that provide the best productive conditions in the manufacture of a product or delivering a service. The quality management system (QMS) that the ISO 9001 standard develops in an organization offers the necessary bases to plan, organize and control such activities considerate critical to meet the requirements of customers, with the support of other standards that cover the essential features of growth and organizational strengthening. This growth can be measured thanks to the benefits that the standard can contribute; however, there are difficulties or barriers that inhibit its implementation due to limitations that organizations may suffer.

Likewise, the ISO 9000 series has served as a basis format to create standard to manage the quality systems in a specific industrial sector that need more rigorous and demanding control. This shows the flexibility and adaptation of the standard to cover all types of industrial activities. On the other hand, comparing the results of the ISO Survey of 2017 and 2018, it can be observed a decrease of certified companies worldwide, and this may be possible due to the evolution that the same standard asks to develop in the certified QMS; this means that organizations have applied tools and controls that improve even more their quality systems obtaining more or better benefits than with the ISO 9001 standard. Also, it would be interesting to find the causality of this phenomenon and recognize which others QMS the organization are applying. Even as an extra contribution, it would be advantageous for the ISO to know which standards are most often implemented in conjunction with the ISO 9001 standard to describe in the new version better and novel requirements.

According to the implementation of the standard in the manufacturing sector in Mexico, the EFA demonstrates how the measuring instrument is suitable for measuring the implementation of the standard in this industrial sector explaining the 69.31% of the phenomenon. With this results, organizations can recognize which factors are essential to successfully implement the ISO 9001 standard and begin obtaining the benefits it provides; however, the results do not show a model that represents the relationship between the factors, so it would be necessary to apply structural equation modeling (SEM) to obtain a structural model that indicates the significant impact between factors associated with the benefits of the standard to recognize exactly the relationship of the constructs that make possible the implementation of the standard ISO 9001 in the manufacturing sector or any business activity.

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