IEEE Access
Multidisciplinary | Rapid Review | Open Access Journal

Received August 28, 2020, accepted September 25, 2020, date of publication October 8, 2020, date of current version October 29, 2020.

Digital Object Identifier 10.1109/ACCESS.2020.3029744

ISO 9001 Standard: Developing and Validating a Survey Instrument

MARCOS ALBERTO SANCHEZ-LIZARRAGA[1], JORGE LIMON-ROMERO[1], DIEGO TLAPA[1], YOLANDA BAEZ-LOPEZ[1], CESAR PUENTE[2], LIZBETH PUERTA-SIERRA[3], AND SINUE ONTIVEROS[4]

[1]Facultad de Ingeniería, Arquitectura y Diseño, Universidad Autónoma de Baja California, Ensenada 22860, México
[2]Facultad de Ingeniería, Universidad Autónoma de San Luis Potosí, San Luis Potosí 78000, México
[3]Facultad de Economía y Negocios, Universidad Anáhuac México, Huixquilucan 52786, México
[4]Facultad de Ciencias de la Ingeniería, Administración y Sociales, Universidad Autónoma de Baja California, Tecate 21460, México

Corresponding authors: Jorge Limon-Romero (jorge.limon@uabc.edu.mx) and Diego Tlapa (diegotlapa@uabc.edu.mx)

ABSTRACT Organizations are in the constant pursuit of reliable strategies for increasing customer satisfaction. One of these strategies refers to the implementation of the ISO 9001 standard as a quality management system to ensure that products and services meet or surpass customer expectations. However, successful ISO 9001-based systems are possible only if companies count on a series of critical success factors that guarantee successful ISO 9001 implementation. This research aims at developing and validating a survey instrument to evaluate the degree of compliance with ISO 9001 critical success factors among manufacturing organizations. The research is conducted in Mexican manufacturing companies. The survey is designed by considering the quality management principles of the ISO 9001:2015 standard as critical success factors. We conducted an exploratory and a confirmatory factor analysis to identify the structure of the survey and confirm its validity. Our findings confirm that the survey instrument comprises four constructs, three of them associated with the quality principles of the ISO 9001 standard, and one associated with the benefits of said standard. In conclusion, the proposed survey is a valid, useful tool to assess ISO 9001 implementation in manufacturing companies and similar organizations.

INDEX TERMS Factor analysis, ISO 9001 standard, manufacturing organizations, quality management system, survey.

I. INTRODUCTION

The quality of a product or service is a reflection of process improvement via business process management [1]. Moreover, quality is one of the main features that companies are committed to attaining at a level that satisfies customer expectations and needs. In this sense, Quality Management Systems (QMSs) are designed and implemented to ensure quality in processes, products, and services, while simultaneously achieving customer satisfaction. There are many definitions of general QMSs. For instance, [2] refer to them as a way to manage an organization to improve its general efficiency, whereas [3] define a QMS as an administrative system used to directly control quality matters to meet organizational goals and objectives. Reference [4] view a QMS and its subsequent certification as a voluntary process adhered to the philosophy of quality and supported by organizational motivation, goals, and policies.

The associate editor coordinating the review of this manuscript and approving it for publication was Shunfeng Cheng.

According to [5], QMSs encompass aspects such as occupational safety and environmental protection and focus on customer and employee health, while simultaneously caring for the needs of society. Garza-Reyes *et al.* [6] consider QMSs as an essential component of organizational performance that provides a range of improvement benefits and has a positive impact on organizations. In addition, [7] conceptualize QMSs as systems certified to ensure that companies have processes in place for various routines, and they theorize that QMSs can support the selection of qualified suppliers, thereby exerting an upstream pressure in the organization. Many QMSs are aligned with international management methodologies and strategies, such as the Malcom Baldrige National Awards (MBNQA), the European Foundation for Quality Management (EFQM), Total Quality Management (TQM), Lean Manufacturing (LM), Six Sigma (SS), Lean Six Sigma (LSS), and the ISO 9001 standard, to name but a few [6], [8]–[10]. In this research, our focus is the international ISO 9001 standard, developed by the International Organization for Standardization (ISO).

Over the years, researchers and industry experts have sought to identify those essential factors that ensure the successful implementation of the ISO 9001 standard among all types of industries [11]–[14] and through multiple different instruments, such as surveys [15]–[18]. The goal of this research is to develop and validate a surveying instrument to assess the degree to which manufacturing companies comply with ISO 9001's Critical Success Factors (CSFs). To this end, the research was conducted in Mexico, and we considered as CSFs the seven Quality Management Principles (QMPs) described by the ISO 9001:2015 standard. The survey was administered among Mexican manufacturing companies to gather the necessary data. Then, we performed an Exploratory Factor Analysis (EFA) and later a Confirmatory Factor Analysis (CFA) to validate the structure of the survey. Our study also discusses those CSFs that senior managers and quality managers view as essential for the proper functioning of QMSs. The remainder of this paper is organized as follows: the following section (section 2) discusses relevant literature on the ISO 9001 standard and its associated CSFs. Section 3 introduces the research methods used to design and validate the survey and the results of the validation process. Then, in Section 4 we discuss the research findings and compare them to those findings reported in similar studies. Finally, in Section 5 we present the limitations and conclusions of the research, as well as our suggestions for future work.

II. LITERATURE REVIEW

A. THE ISO 9001 STANDARD

The ISO was founded in 1947, and since then, it has developed more than 21,000 international standards for all aspects of technology and manufacturing [19]. ISO is an independent, international nongovernmental organization (NGO) established in Geneva, Switzerland, working through a network of 164 National Standards Bodies (NSB), each one representing one-member country and being recognized as an authority on standards in that country. ISO standards are developed by groups of experts from Technical Committees (TCs). Each TC deals with a different subject and is made up of representatives of NGOs, industry, governments, and other stakeholders, who are put forward by ISO's members [20].

The first ISO 9000 series for international quality management was published in 1987 and managed by TC 176. The ISO 9000 series is the most recognized and implemented set of Quality Management System (QMS) standards, and it seeks to enable a mutual understanding of and compliance with quality requirements in national and international trade [21]. Additionally, the ISO 9000 series helps organizations – regardless of their type or size – to achieve and preserve customer satisfaction, meet regulatory requirements, and attain continuous improvement [22]. The most recent version of the ISO 9001 standard – the ISO 9001:2015 – specifies requirements for adequate quality management to help organizations meet and exceed customer expectations [23]. In other words, organizations use the standard to demonstrate their ability to 1) perform within its working systems and 2) consistently provide products that meet customer expectations and applicable statutory and regulatory requirements, while simultaneously committing to continuous improvement [24].

The ISO 9001:2015 standard is considered a way for attaining competitive benchmarking in the industry. It has three mains scopes: process approach, risk-based thinking, and the seven quality management principles (QMPs) [25], [26]. The process approach relies on the PDCA cycle (Plan-Do-Check-Act) to allow organizations to better plan their internal processes. Also, [27] detail how the ISO 9001:2015 standard takes the process approach to improve organizational performance with a specific focus on quality management, process control, and quality assurance techniques. On the other hand, risk-based thinking enables organizations to find those circumstances that may cause troubles or malfunctions in their QMSs in order to put in place preventive controls to minimize negative effects and make the most use of opportunities as they arise.

The literature proposes multiple definitions of the ISO 9001 standard. For instance, [28] conceive it as the most prevalent management standard certification for a wide range of organizations. In turn, [29] views ISO 9001 as a standard used for external quality assurance purposes, designed for internal use, and focused on quality aspects in the production of products or services. According to [30], the performance of the ISO 9001 standard includes long term contributions and potentially positive, neutral, or negative effects, depending on the organization's objectives. Anttila and Jussila [31] claim that the starting point when implementing ISO 9001 involves companies identifying the needs of their QMSs. In fact, as [32] argue, the standard is a provider of an excellent framework that empowers organizations to develop customized QMSs to facilitate the optimal arrangement of valuable resources into their key processes. In the context of Small and Medium Enterprises (SMEs), [33] describes ISO 9001 as one of the approved strategies to handle external pressure and overcome the liabilities of newness and smallness. Additionally, ISO 9001 is considered to be the first step to develop a QMS and encourages organizations to work within a culture of continuous improvement [29], [34], [35].

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. Consequently, it is an important contribution to improve product/service performance [36]. In the context of performance improvement, the literature reports numerous studies on ISO 9001 implementation. For instance, both [37] and [38] described a positive relation between the implementation of ISO 9001 and organizational performance. Likewise, [39] described how the implementation of ISO 9001 in refueling services at an airport reduced average monthly incidents by 45.2%. In their work, [40] found that ISO 9001 implementation in the food industry helps companies efficiently control resources and processes to finally attain international and economic growth. On the other hand, the literature also reports how organizations fail in the implementation of the ISO 9001 standard and other QMSs [41]–[44]. Such results reveal the need of a rigorous analysis to 1) identify which elements or factors are crucial to the successful implementation of any QMS and 2) design efficient surveying tools to help organizations to determine to what extent they comply with these factors. This research seeks to address these needs. ISO 9001 provides theoretical and practical knowledge for QMS development by making all departments aware of the importance of continuous improvement in terms of meeting customer requirements and needs. According to [24], the greatest value of the ISO 9001 comes from using the entire ISO 9000 standard family in an integrated manner. Similarly, it is highly recommended that organizations working under ISO 9001 become acquainted with the fundamental concepts, principles, and normative vocabulary of a QMS before adopting the standard in order to attain an effective level of performance.

B. CRITICAL SUCCESS FACTORS

In their pursuit of adequate quality management, organizations seek to identify and comply with those factors ensuring successful ISO 9001 implementation. In the literature, such factors are conceptualized as Critical Success Factors (CSFs). According to [45], CSFs can be defined as the essential components that organizations need to possess in order to obtain the greatest advantages and competencies to be able to attain the proper implementation of a QMS. In other words, CSFs are the characteristics or elements that organizations need to have and maintain so that their QMSs are satisfactory implemented in all processes and systems [6]. According to [46]–[48], CSFs can also be viewed as those components that organizations seek to identify and develop in their processes in order to recognize which areas will produce the greatest competitive advantages. Finally, according to Rockart (1979), cited by [49], CSFs are the set of factors necessary for an organization to achieve its goals successfully. If these factors are not prioritized, completed, or fulfilled when companies embark in new projects, such projects are likely to fail.

In this research, we conducted an extensive literature review to identify those CSFs that allow organizations to successfully implement a QMS following the ISO 9001 [12], [26], [30], [34], [50]–[60]. After ISO 9001 was updated in 2000, ISO 9001:2015 began to emphasize on the concept of principles. In this sense, a principle is defined as a basic belief, theory, or rule that has a major influence on the way organizations perform their activities. In turn, Quality Management Principles (QMPs) are the set of fundamental beliefs, rules, and values that can be used as the basis for quality management and performance improvement [22]. In this sense, the CSFs for ISO 9001 implementation reported in the literature essentially agree with the QMPs introduced in the ISO 9001:2015 standard. Consequently, this research considers these QMPs as the CSFs for ISO 9001 implementation. Hence, we recognize them as the mandatory elements that every organization must comply with to increase the success of ISO 9001 projects. Next, we list the QMPs or CSFs for ISO 9001 implementation, along with their corresponding definitions. These definitions are based on what is stated by [26] and [22]:

- *Leadership (LD):* Leaders at all levels establish unity of purpose and direction to create the conditions in which people engage to attain the organization's quality objectives.
- *Customer Focus (CF):* The primary goals of quality management are to achieve customer satisfaction and to strive to exceed their expectations.
- *Engagement of People (EP):* Competent and empowered people are essential to enhance the ability of an organization 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 functioning as a coherent system.
- *Improvement (IMP):* Successful organizations have an ongoing improvement focus.

Evidence-Based

- *Decision Making (EDM):* A decision-making system based on data analysis and evaluation is more likely to produce desired results.
- *Relationship Management (RM):* For sustained success, organizations manage their relationships with interested parties.

III. METHODS AND RESULTS

This section describes the steps followed to design and validate the surveying instrument, as well as the results from the validation process. These steps comprise survey design and administration, data statistical analysis to verify our assumptions, data analysis through factor analysis, and construct validity. This method has been adopted in similar works for instrument development and validation [15], [61]–[63]. It is important to mention here that all the statistical analyses performed to verify the assumptions as well as to realize the exploratory and confirmatory factor analysis were carried out using the IBM SPSS 23® Software and AMOS package.

A. INSTRUMENT DESIGN AND ADMINISTRATION

One of the most important steps of this research was to identify the constructs or factors to be studied. To this end, we conducted a literature review of CSFs for ISO 9001 implementation. The search was conducted in five databases: Emerald, Taylor & Francis, EBSCO, Elsevier, and Springer. As one of the inclusion criteria, we only searched for papers published no later than 2000. Hence, the review mainly included literature on ISO 9001:2000, ISO 9001:2008, and ISO 9001:2015. These versions of the standard are the only ones that describe the QMPs. Additionally, we used multiple keywords for the search of primary sources, including ISO 9001 standard; ISO 9001 standard AND manufacturing organizations AND critical success factors; and quality management system AND critical success factors. Finally, we collected 86 primary sources for the reviewing process. As previously mentioned, the seven CSFs selected correspond to the seven QMPs of ISO 9001:2015. As for the items, these were selected according to their relevance to and relationship with the seven CSFs.

The survey comprises three sections. The first section of the survey consisted of 10 demographic items. The second section of the survey lists 25 items—variables LD, CF, PA, and EDM have four items each, whereas EP, IMP, and RM comprise three items each. On the other hand, the third section of the survey lists five items related to ISO 9001 Benefits (BEN). Both the second and the third section of the survey must be answered with a five-point Likert scale (1: never, 2: rarely, 3: regularly, 4: almost always, 5: always). The survey is aimed at companies within manufacturing organizations that have or have previously held an ISO 9001 certification. The survey is mainly intended for quality managers or manufacturing managers; however, senior managers directly working with a QMS are also considered a part of the target population. The survey was designed and administered in an electronic format using the Surveygizmo platform, and it was shared with potential respondents via email and social media platforms, including LinkedIn. We collected a total of 537 responses. However, not all of them were completely or correctly answered; therefore, we could only use 120 of them since only these were correctly completed and provided the needed information to perform the statistical analysis involved in the validation process. Table 1 summarizes the content of Sections 2 and 3 from the survey (CSFs or QMPs and Benefits), along with their corresponding items. Note that the items comprising variable BEN were selected from the literature review according to their frequency of occurrence during the search [35], [50], [59], [64]–[68].

B. CRITICAL ASSUMPTIONS FOR DATA VALIDATION

According to [69] and [70], there are four important issues to consider in any survey validation process: missing data, outliers, univariate and multivariate normality assumptions, and multicollinearity. The critical assumptions underlying factor analysis are more conceptual than statistical, but in this technique, the primary concerns are both the character and composition of the variables included in the analysis, as well as their statistical qualities [69]. Missing data occur when respondents do not rate or give an answer to a given item. Fortunately, since we administered the survey in its electronic version, we labeled all the questions as mandatory on the website's bulk editor, thus avoiding any potential missed responses. On the other hand, we managed to detect outliers using Mahalanobis distance (D^2), which measures the distance of each observation in a multidimensional space from the centroid of all observations, providing a unique value for each observation [69].

Hair *et al.* [69] and Kline [70] claim that high D^2 values represent the furthest observations from the general distribution in the dimensional plane. Additionally, [70] argues that observations with a P-value smaller than 0.001 should be removed from the analysis. In this research, we removed six responses based on the P-values reported by AMOS software, thus leaving 114 useful surveys for further analysis. In regards to the normality assumption, although the variables of the survey instrument were measured in an ordinal scale, following [69] and [70], univariate and multivariate normality assumptions must be verified. For the univariate normality assumption, we calculated the kurtosis index for each variable. Kline [70] claims that kurtosis values greater than 10.0 could represent a problem, whereas values greater than 20.0 indicate a serious problem. Among the results of our sample, shown in Table 2, the kurtosis values ranged from -0.948 to 7.423; hence, we confirmed that univariate normality was fulfilled in each variable. As for multivariable normality assumptions, multiple studies recommend Mardia's measure for multivariate kurtosis [61], [62], [72], [73]. Hence, we verified multivariable normality by comparing Mardia's coefficient for the data under study to a calculated value based on the formula $p^*(p+2)$, where p is the number of variables observed in the model. Then, this assumption is verified by contrasting the multivariable kurtosis value obtained on SPSS Amos against that obtained with the proposed formula [74]. The calculation was performed assuming 30 variables. The formula yielded a value of 960, whereas the SPSS Amos Mardia's multivariate kurtosis index was 192.18. Therefore, since Mardia's coefficient was smaller than the value from the formula, we concluded that the multivariate normality assumption was confirmed. Finally, multicollinearity occurs when correlation values between variables are greater than 0.85. Values higher than 10 in the Variance Inflation Factor (VIF) indicate a problem of multicollinearity among variables [70]. Fortunately, we did not find any value greater than 0.85 in the correlation matrix, in which the largest correlation value was 0.756. Additionally, as Table 2 shows, the obtained VIF values ranged from 1.918 to 5.204. Hence, we confirmed that the latent variables were free from multicollinearity problems.

C. FACTOR ANALYSIS

Once the data were collected and the statistical assumptions were verified, we performed an Exploratory Factor Analysis (EFA) and then a Confirmatory Factor Analysis (CFA) for validation purposes. Factor Analysis (FA) is an interdependence technique whose main objective is to define the underlying structure among the variables in the analysis [69]. FA can be conducted under an exploratory approach (EFA) or a confirmatory approach (CFA). We performed an EFA to identify the structure of the survey and recognize the potential factors that could emerge as grouping items that are

TABLE 1. Survey instrument.

Construct	Item	Variable
Leadership	Management conducts regular inspections of quality performance on products/services [55].	LID1
	Internal quality audits verify quality system effectiveness [67].	LID2
	Management shares information and promotes collaboration among departments [96].	LID3
	Staff is trained in ISO 9001 requirements [55].	LID4
Engagement of people	Recognition/rewards programs yield good results in terms of staff performance [67].	EP1
	Employees are encouraged to develop new ways to do their job better [55].	EP2
	Staff receives adequate training [55].	EP3
Improvement	The organization has clearly-established quality goals [55].	IMP1
	The planning process includes continuous quality improvement [55].	IMP2
	All staff in all areas is focused on making continuous improvement efforts [56].	IMP3
Customer Focus	Product quality is measured by customer satisfaction [67].	CF1
	Causes of customer attrition are identified [55].	CF2
	There is a systematic process for handling customer complaints [67].	CF3
	The company collects information on customer perceptions of product requirements, expectations, and needs [56].	CF4
Process Approach	There is a strong emphasis on internal customer/supplier relationships [67].	PA1
	Error prevention is a part of the company's work culture [55]	PA2
	Error correction is always considered in daily operations [55].	PA3
	Defective products are handled separately to prevent misuse or delivery [56].	PA4
Evidence-Based Decision Making	Information on quality issues is always timely reported [67].	EDM1
	Data collected from measurements are analyzed [56].	EDM2
	Quality issues are top priority as criteria when making decisions [55].	EDM3
	Project teams take part in the decision making process [96].	EDM4
Relationship Management	Company criteria for supplier selection and evaluation are determined [56].	RM1
	Quality is the main criterion for choosing suppliers [67].	RM2
	The company seeks to have long-term stable relationships with its suppliers [67].	RM3
Benefits	Customer satisfaction has increased.	BEN1
	Errors/defects have decreased.	BEN2
	Waste /activities adding no value to products are minimized.	BEN3
	Effectivity in top management decision making has increased.	BEN4
	Employees are increasingly integrated into the continuous improvement culture.	BEN5

correlated. To determine whether FA was feasible, we performed Bartlett's test of sphericity and the Kaiser-Mayer-Olkin (KMO) test for sampling adequacy. We used Bartlett's test of sphericity to tests the null hypothesis, in which the correlation matrix of the variables is equal to the identity matrix [69]. On the other hand, we used the Kaiser-Mayer-Olkin (KMO) test to verify the suitability of our sample for FA [74]. KMO values greater than 0.7 are considered regular, values above 0.8 are good, and values beyond 0.9 are very good. In other words, if the KMO test results in a small number or a number very close to zero, the sample cannot be used for a FA [69]. Additionally, we calculated the Cronbach's alpha index to measure the reliability and internal consistency of the survey constructs according to Hair *et al.* [69].

D. EXPLORATORY FACTOR ANALYSIS

We performed an EFA to analyze the grouping structure of the survey variables. We used Bartlett's test of sphericity on the 30 variables referring to the CSFs, thus obtaining a chi-square of 2389.294 with 435 degrees of freedom (df) and a P-value of 0.00. Such results helped us reject the null hypothesis and indicated that the correlation matrix was different from the identity matrix. Then, we performed the KMO test, whose results indicated that the database was suitable for FA. Finally, for the extraction method, we relied on both the principal components analysis (PCA) and Varimax rotation, broadly reported in the literature [72], [75]–[77]. Following the EFA, we removed eight variables from the analysis to avoid cross loadings. The EFA results identified 22 variables with significant loadings on four different factors with eigenvalues greater than 1. These significant loadings were greater than 0.4 and considered important for determining the influence of each item on the factor relative to the sample size [69]. Table 3 shows the factor loadings of each variable along with the corresponding eigenvalues associated to each factor. According to these results, the grouping behavior of

TABLE 2. Kurtosis and VIF values to verify normality and multicollinearity assumptions, respectively.

Factor	Variable	Kurtosis	VIF
LID	LID1	2.137927	3.371
	LID2	0.769820	2.465
	LID3	0.410658	2.908
	LID4	-0.200560	2.631
CF	CF1	7.227201	2.334
	CF2	2.575371	2.137
	CF3	4.716918	2.368
	CF4	2.099131	3.222
EP	EP1	-0.948810	3.246
	EP2	-0.274660	4.886
	EP3	-0.391210	3.051
PA	PA1	-0.701320	3.187
	PA2	-0.336900	4.802
	PA3	-0.317370	3.246
	PA4	7.423551	1.918
IMP	IMP1	0.435553	5.204
	IMP2	1.602726	4.355
	IMP3	-0.676080	3.278
EDM	EDM1	-0.637950	2.709
	EDM2	1.655413	3.726
	EDM3	0.404137	3.974
	EDM4	0.353526	3.395
RM	RM1	0.414425	2.993
	RM2	0.071958	3.813
	RM3	-0.544440	3.215
BEN	BEN1	-0.022410	2.716
	BEN2	0.199115	3.315
	BEN3	-0.638140	2.279
	BEN4	-0.351400	3.457
	BEN5	-0.551820	3.603

the variables is notably structured by their own approach. For instance, the items belonging to Leadership (LID), Customer Focus (CF), and Process Approach (PA) showed significant factor loadings on the same constructs. Consequently, these three QMPs were considered as one factor, Top Management Commitment (TMCM) [12], [78]. Similarly, the items related to Improvement (IMP), Evidence-based Decision Making (EDM), and Relationship Management (RM) loaded all together on the same construct. Hence, these QMPs were grouped together as a single construct named System Improvement (SI) [79], [80]. Finally, items related to Engagement of People (EP) and, Benefits (BEN) loaded on their corresponding factors without elements from other factors. Hence, these items were kept in their respective original constructs. As seen in Table 3, we also calculated the Cronbach's alpha coefficient for each factor. The alpha coefficient of reliability ranges from 0 to 1. Values close to 1 indicate better factor internal consistency, whereas values lower than 0.70 would question the reliability of the survey [81]. All the factors analyzed in this research demonstrated an acceptable reliability value. Moreover, considering the four research constructs, the total explained variance was above 65%, thus indicating that more than 50% of the total variance could be explained by the selected factors.

TABLE 3. Factor loadings of each variable and its corresponding eigenvalues.

Variable	Factor				Eigen Values	Cronbach's Alpha
	SI	TMCM	BEN	EP		
IMP2	.695				9.957	0.915
IMP3	.586					
PA4	.693					
RM2	.673					
RM3	.663					
EDM3	.612					
EDM4	.659					
IMP1	.774					
LID2		.762			1.986	0.846
LID3		.683				
LID4		.763				
PA1		.489				
CF1		.643				
CF4		.589				
BEN1			.761		1.340	0.863
BEN2			.774			
BEN3			.700			
BEN4			.838			
BEN5			.681			
EP1				.813	1.154	0.840
EP2				.852		
EP3				.556		

E. CONFIRMATORY FACTOR ANALYSIS

Once we confirmed the feasibility of FA, and after performing the EFA, we tested the validity of the constructs through a CFA. To evaluate construct validity, Hair *et al.* [69], recommend performing convergent, discriminant, and nomological validity. The importance of evaluating the quality of the results lies in ensuring the validity of the conclusions obtained from the exploratory analysis [69]. In this sense, a CFA seeks to find the degree to which the theoretical pattern of factor loading in specific dimensions represents the real data taken for the sample [72]. That is, CFA is used to provide a confirmatory test of measurement theory, specifying how the measured variables logically and systematically represent the construct involved in a theoretical model [69]. The measurement model specifies a series of relationships that suggest how the measured variables represent a latent construct which, by definition, is not directly measured.

The loading structure of the QMPs took place in the EFA, which helped us classify such principles into three main factors or enablers: TMCM, EP, and SI. These three constructs can be considered as essential elements that manufacturing companies need to possess and maintain to ensure the successful implementation of ISO 9001 and thus obtain its benefits (BEN). However, according to Hair *et al.* [69], the validity of a measurement model depends on acceptable levels of goodness of fit (GoF), which indicates how well a specified model reproduces the covariance matrix between the variables. Likewise, Kline [70] and Hair *et al.* [69], claim that it is important to report at least one incremental index and an absolute index, in addition to the Chi-square values and the associated degree of freedom (df). Therefore, by calculating the Chi-square (χ^2) value, along with the Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and the Root Mean

Square Error of Approximation (RMSEA), researchers have enough information to evaluate a model and verify whether it accurately represents the specified relations among items and factors. Table 4 below lists the model fit indices obtained in the CFA, along with the recommended values for acceptable model fit. According to these results, we confirmed the validity of the measurement model and hence demonstrated that the measured variables truthfully represent the factors involved. Finally, Fig. 1 illustrates our measurement model.

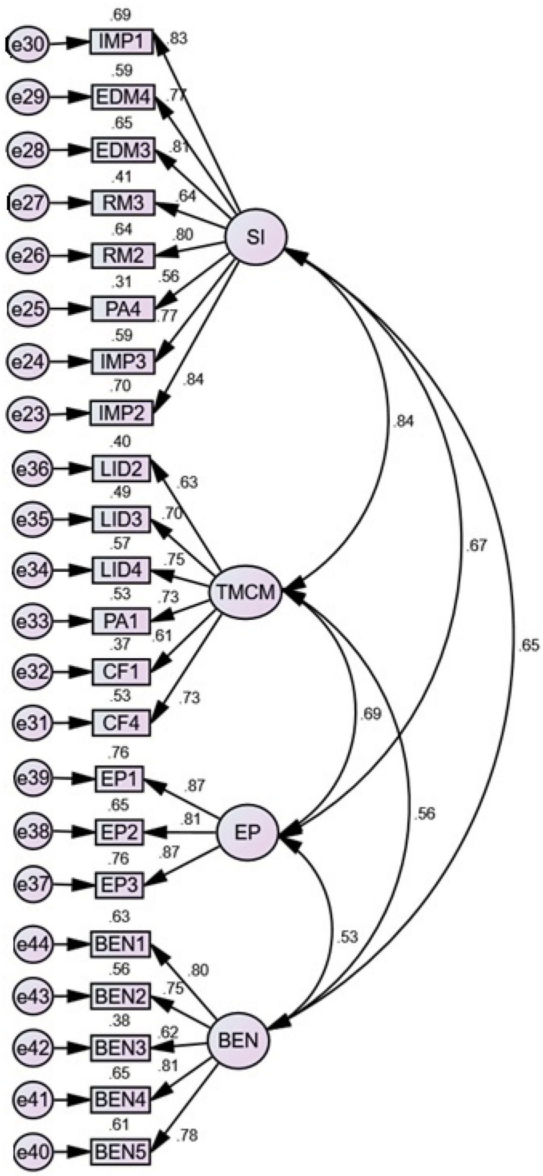

FIGURE 1. Proposed measurement model.

F. CONSTRUCT VALIDITY

According to Hair *et al.* [69], validity is the degree to which a measure accurately represents what it is supposed to measure. To assess construct validity, we performed both a convergent validity test and a discriminant validity test. A given set of variables can measure the same construct if the convergent validity between its correlations is at least moderate in magnitude; on the contrary, it is assumed that a set of variables measures different constructs if the discriminant validity in their correlations is not high [70]. Enough convergent validity implies that the Average Variance Extracted (AVE) value in each latent variable is higher than 0.5 [69], whereas enough discriminant validity implies that the AVE values are higher than the squared correlation between dimensions, thus confirming that two constructs are independent from one another [62]. Table 5 lists the AVE values in the main diagonal of the correlation matrix. As can be observed, all the values are greater than 0.5; therefore, we confirmed the convergent validity of the constructs. As for discriminant validity, we removed seven variables to validate the factors. According to Table 5, almost all the constructs had an AVE value greater than the squared correlation values showed above the main diagonal, with the exception of TMCM related with SI; however, at least one of the AVE values of these constructs is greater than the corresponding squared correlation. This demonstrates the discriminant validity of each factor involved in the questionnaire. All the GoF indices showed satisfactory values with respect to those recommended by [69] and [82]. Finally, Table 5 also lists the correlation values of each factor below the main diagonal. These are all statically significant at a 0.001 confidence level, thus confirming that the factors are positively and significantly interrelated.

TABLE 4. Model fit indices estimated for the measurement model.

Goodness of fit statistics	Obtained value	Recommended values for a satisfactory model fit
CHI-SQUARE (X^2)	1.502, (199 df)	Lower than 3.0 [69], [82]
TLI	0.920	Higher than 0.90 [82]
CFI	0.931	Higher than 0.90 [82]
RMSEA	0.067	Lower than 0.08 [69], [82]

TABLE 5. Correlations among constructs, average variance extracted and square correlations.

Factor	TMCM	EP	SI	BEN
TMCM	**0.547**	0.467	0.662	0.352
EP	0.683	**0.732**	0.386	0.284
SI	0.814	0.622	**0.670**	0.345
BEN	0.594	0.533	0.588	**0.545**

Note: Values below the diagonal are correlation estimates among constructs all statistically significant at 0.001, diagonal values (bolded) are constructs Average Variance Extracted (AVE) and values above the diagonal are squared correlations

G. DEMOGRAPHIC DATA ANALYSIS

Among the characteristics of the sample, we found that the states with the largest participation in the study included Baja California at 38.33% and Guanajuato at 10.00%, along with The State of Mexico, Sonora, and Sinaloa at 5.83%, each. Even though the National Statistical Directory of

Economic Units (DENUE, for its acronym in Spanish) has more industries registered in The State of Mexico than in Guanajuato or Baja California, the fact that we are based in Baja California helped us gather more data from said state than from other parts of the country, including The State of Mexico. As for the surveyed sectors, we relied on DENUE's classification of manufacturing industries to classify the sample. In this sense, the most representative industries in the study included the medical equipment manufacturing industry and the dental and ophthalmic manufacturing industry, accounting for 26.67% of the sample. Additionally, the machinery and equipment manufacturing industry represented 22.0% of the sample, followed by oil and coal derivate manufacturers and chemical plastic and rubber industries, with 15.00%. The metal industry had a participation of 11.67% in the study, followed by the food, beverage, and tobacco industry (10.83%). The nonmetallic mineral-based product industry, the textile, clothing and leather industry, and other industrial sectors represented only 2.50%, 1.67%, and 9.17% of the sample, respectively. Finally, as regards company size, 60.00% of the sample concerned large manufacturing industries, whereas medium and small companies were represented in 24.17% and 13.33%, respectively.

IV. DISCUSSION

The goal of this research was to develop and validate a measurement instrument that defines the CSFs for ISO 9001 implementation in the manufacturing industry. Our results reveal that four constructs could be used to measure successful ISO implementation in said industry: top management commitment (TMCM), system improvement (SI), engagement of people (EP), and ISO benefits (BEN). Also, according to our results, the seven QMPs could be grouped into three factors – TMCM, SI, and EP – that enable companies to effectively implement the standard and gain the corresponding benefits (BEN). Our findings are consistent with those reported by Bastas and Liyanage [80], who report leadership, employee engagement, and process improvement as the main CSFs to integrate ISO 9001 in supply chain management. TMCM is considered as a support factor for ISO 9001 implementation [83]. In their work, Doronina *et al.* [84] claim that top management support may trigger employee engagement in the accomplishment of the ISO 9001 standard, whereas [85] described how both top management leadership and the engagement of people allow for the implementation of the ISO 9001 standard. In fact, leadership is said to be one of the main characteristics to arrange a QMS into those work procedures that develop organizational goals and objectives [15], [25], [86], [87]. Finally, the ISO 9001:2015 standard requirements manual [22] states that leadership, engagement of the people, customer focus, process approach, evidence-based decision making, process improvement, and relationship management are the key factors for the effective implementation of the standard. At this point, it is important to highlight that despite some similarities between our findings and those reported in other works in the literature, these similarities are partial because previous works did not exactly describe the three enablers we reported; additionally, none of the previous works report a statistically validated survey instrument that uses as a reference the seven QMPs according to the ISO 9001:2015 requirement manual. Based on these facts, we can say that the findings reported here add new insights to the existing literature related to quality management systems.

As regards SI, Brajer-Marczak [88] argues that organizations focused on processes improvement are able to constantly respond to changing customer requirements and expectations. Likewise, [15] described how food manufacturing companies attain the objectives of the ISO 9001 standard by focusing on continuous improvement, preventing nonconformities, and adopting a customer satisfaction focus. In addition, continuous improvement is considered a support factor for ISO 9001 implementation [83]. Furthermore, [89] stated that quality awareness, which is the basis for decision making, and knowledge management are factors affected by the implementation of ISO 9001.

Finally, EP as a CSF for ISO 9001 implementation has been thoroughly studied [80], [83]. Reference [90] claim that both staff management and strategic planning for quality improvement should be prioritized when implementing ISO 9001. In turn, [52] mention that ISO 9001 certified organizations are acknowledged for their highly engaged personnel and their effective approach to fulfilling the standard guidelines. Finally, the ISO 9001:2015 standard requirements manual [22] states that leadership, engagement of the people, customer focus, process approach, evidence decision making, process improvement, and relationship management are the key factors for the effective implementation of the standard. Despite some similarities from findings reported in other works in literature, these are partial because previous work do not described exactly the same three enablers we are reporting; additionally, any of those works do not report a survey instrument taking as reference the seven QMPs according to ISO 9001:2015 requirement manual.

In terms of industry size, our results are also consistent with those reported in the literature. For instance, [26], [38], [91] described company size as an impelling factor in the implementation of ISO 9001. Jasarevic *et al.* [92] also agree that company size certainly influences the implementation of the standard, as large companies usually obtain better results with greater tolerance to changes due to the introduction and the subsequent maintenance of the QMS. In this sense, [87] suggests that SMEs should learn from the QMS implemented in large companies.

The literature reports similar ISO 9001 CSFs across different sectors. In their work, [73] validated a survey instrument to evaluate the impact of ISO 9001 in schools using factor analysis. Similarly, [93] described how supplier relationship for quality inputs, employees engaged to accomplish goals, and top management contribute to an effective quality management culture in TQM. Also, [94] claim that knowledge management is a significant factor for TQM, whereas [76] found top management, process management, and supplier quality management as some of the essential factors for assessing quality management in hospitals. In turn, [95] proposed a survey instrument for TQM implementation and highlighted both process management and human resource involvement as the most important CSFs. In their work, Maciel-Monteon *et al.* [62] described how cultural change, top management involvement and commitment, training and education, and linking SS with customers are the CSFs for SS implementation in higher education institutions. Finally, [48] found that employee involvement and management commitment are two of the CSFs for effective implementation of Lean Six Sigma (LSS) in SMEs.

V. LIMITATIONS AND FUTURE WORK

The major limitation of this research refers to the study population, since the sample only comprised quality and/or manufacturing managers as well as senior managers related to the QMS. Such a reduced sample entails the risk of biased results. Also, the survey was validated only among manufacturing companies located in Mexico; hence, it is important to analyze the feasibility of validating the survey in other manufacturing kind of industries as well as in other countries. Likewise, since most of the data were collected from large companies, our findings may have a limited interpretation. As regards our suggestions for future work, we believe that further research should be conducted to develop a longitudinal study and describe how CSFs for ISO 9001 implementation evolve in time in the manufacturing industry. Additionally, future research works may intend to administer and validate the survey in the service industry to compare the ISO 9001 CSFs of the tertiary sector with those identified for the industrial sector. Possible future research could also incorporate new critical factors into the survey with respect to the ISO 9001 QMPs. Finally, an important contribution to this research would be to develop a structural model to identify the relationships and interactions between the constructs that enable the successful implementation of ISO 9001 in manufacturing organizations.

VI. CONCLUSION

Organizations are in the constant pursuit of those practices that provide the best manufacturing conditions. The QMS that ISO 9001 helps develop sets the grounds for planning, organizing, and controlling those activities that are essential for meeting internal and external customer requirements and ensure organizational growth and strength. Our findings confirm that three constructs – TMCM, SI, and EP – represent the factors that increase the likelihood of successful ISO 9001implementation in the manufacturing industry. Likewise, the three enablers representing the model indicate that ISO 9001 should be implemented with enough effort and knowledge to fulfill and exploit the qualities of these factors and consequently obtain the benefits (BEN) of the standard, including organizational performance. In other words, top management should lead the customer focus through the internal improvement of the organization by ensuring employees are engaged to meet quality objectives and through assertive decision-making. Moreover, proper supplier selection and evaluation ensure the quality of the inputs. In the end, the benefits of prosperous ISO 9001 projects will be visible through the organization's performance indices. Then, these organizations would be acknowledged for their ability to comply with and maintain those essential elements that guarantee the implementation of ISO 9001 and their corresponding benefits.

REFERENCES

[1] D. J. Elzinga, T. Horak, C.-Y. Lee, and C. Bruner, "Business process management: Survey and methodology," *IEEE Trans. Eng. Manag.*, vol. 42, no. 2, pp. 119–128, May 1995, doi: 10.1109/17.387274.

[2] L. J. Porter and A. J. Parker, "Total quality management—The critical success factors," *Total Qual. Manag.*, vol. 4, no. 1, pp. 13–22, 1993, doi: 10.1080/09544129300000003.

[3] J. Juran and A. Godfrey, *Juran's Quality Handbook*. New York, NY, USA: McGraw-Hill, 1998.

[4] L. Bravi, F. Murmura, and G. Santos, "The ISO 9001:2015 quality management system standard: Companies' drivers, benefits and barriers to its implementation," *Qual. Innov. Prosperity*, vol. 23, no. 2, pp. 64–82, 2019, doi: 10.12776/QIP.V23I2.1277.

[5] A. Gargasas, M. Samuolaitis, and I. Mugiene, "Quality management system in logistics," *Manag. Theory Stud. Rural Bus. Infrastruct. Dev.*, vol. 41, no. 2, pp. 290–304, 2019, doi: 10.5772/intechopen.71431.

[6] J. A. Garza-Reyes, L. Rocha-Lona, and V. Kumar, "A conceptual framework for the implementation of quality management systems," *Total Qual. Manage. Bus. Excellence*, vol. 26, nos. 11–12, pp. 1298–1310, Dec. 2015, doi: 10.1080/14783363.2014.929254.

[7] P. Hallberg, N. Hasche, J. Kask, and C. Öberg, "Quality management systems as indicators for stability and change in customer-supplier relationships," *IMP J.*, vol. 12, no. 3, pp. 483–497, Nov. 2018, doi: 10.1108/imp-01-2018-0006.

[8] S. M. Dahlgaard-Park, "The quality movement: Where are you going?" *Total Qual. Manage. Bus. Excellence*, vol. 22, no. 5, pp. 493–516, May 2011, doi: 10.1080/14783363.2011.578481.

[9] K. Moosa and A. Sajid, "Critical analysis of six sigma implementation," *Total Qual. Manage. Bus. Excellence*, vol. 21, no. 7, pp. 745–759, Jul. 2010, doi: 10.1080/14783363.2010.483100.

[10] H. Sun, S. Li, K. Ho, F. Gertsen, P. Hansen, and J. Frick, "The trajectory of implementing ISO 9000 standards versus total quality management in western Europe," *Int. J. Qual. Rel. Manage.*, vol. 21, no. 2, pp. 131–153, Feb. 2004, doi: 10.1108/02656710410516952.

[11] L. M. Fonseca and J. P. Domingues, "Listen to ISO 9001:2015 for organizational competitiveness: Correlation between change management and improvement," in *Proc. Int. Conf. Bus. Excell.*, 2017, vol. 11, no. 1, pp. 916–926, doi: 10.1515/picbe-2017-0097.

[12] V. Ismyrlis, O. Moschidis, and G. Tsiotras, "Critical success factors examined in ISO 9001:2008-certified Greek companies using multidimensional statistics," *Int. J. Qual. Rel. Manage.*, vol. 32, no. 2, pp. 114–131, Feb. 2015, doi: 10.1108/IJQRM-07-2013-0117.

[13] B. Neyestani and J. B. Juanzon, "Effects of ISO 9001 standard on critical factors of project management in construction industry," *SSRN Electron.*, pp. 53–57, Jan. 2018.

[14] F. Tigre-O, E. E. Tubon-Nunez, S. Carrillo, J. Buele, and F. Salazar-L, "Quality management system based on the ISO 9001:2015: Study case of a coachwork company," in *Proc. 14th Iberian Conf. Inf. Syst. Technol. (CISTI)*, Jun. 2019, pp. 19–22, doi: 10.23919/cisti.2019.8760816.

[15] E. L. Psomas, D. P. Kafetzopoulos, and C. V. Fotopoulos, "Developing and validating a measurement instrument of ISO 9001 effectiveness in food manufacturing SMEs," *J. Manuf. Technol. Manage.*, vol. 24, no. 1, pp. 52–77, Dec. 2012, doi: 10.1108/17410381311287481.

[16] K. A. Razali and A. Saaban, "A descriptive perception vs achievement analysis of continuance improvement on Malaysian ISO 9001 certified companies," in *Proc. ASIA Int. Multidiscip. Conf. (AIMC)*, vol. 7, 2017, pp. 553–556.

[17] C. M. Sedani and R. R. Lakhe, "Critical factors to attain ISO 9000 certification: A survey of Indian SMEs," in *Proc. 2nd Int. Conf. Emerg. Trends Eng. Technol.*, 2009, pp. 765–774, doi: 10.1109/ICETET.2009.65.
[18] S. Sousa and E. Aspinwall, "Development of a performance measurement framework for SMEs," *Total Qual. Manage. Bus. Excellence*, vol. 21, no. 5, pp. 475–501, May 2010, doi: 10.1080/14783363.2010.481510.
[19] International Organization for Standardization. *ISO—The ISO Story*. Accessed: Oct. 23, 2019. [Online]. Available: https://www.iso.org/the-iso-story.html
[20] D. Hoyle, *ISO 9000 Quality Systems Handbook: Increasing the Quality of an Organization's Outputs*, 7th ed. New York, NY, USA: Routledge, 2018.
[21] H. C. Salagean, R. D. Gârbacea, E. Emmanouilidis, and O. Marian, "From ISO Standards To TQM Philosophy," *Manag. Challenges Contemp. Soc.*, vol. 7, no. 2, pp. 93–98, 2014. [Online]. Available: http://eserv.uum.edu.my/docview/1637637048?accountid=42599
[22] *Quality Management Systems—Requirements*, Standard ISO 9001, International Organization for Standardization, 2015.
[23] A. Wecjenmann, V. Majstorovic, G. Akkasoglu, and T. Werner, "Quality management–history and trends," *TQM J.*, vol. 27, no. 3, pp. 281–293, 2015, doi: 10.1108/TQM-11-2013-0125.
[24] *Selection and use of the ISO 9000 Family of Standards*, Int. Org. Standardization, Geneva, Switzerland, 2016.
[25] B. Manders, H. J. de Vries, and K. Blind, "ISO 9001 and product innovation: A literature review and research framework," *Technovation*, vols. 48–49, pp. 41–55, Feb. 2016, doi: 10.1016/j.technovation.2015.11.004.
[26] L. Farinha, J. Lourenço, and C. Caroço, "Guidelines for the implementation of a quality management system in industrial companies," *Romanian Rev. Precis. Mech., Opt. Mechtron.*, vol. 50, no. 1, pp. 195–201, 2016.
[27] G. Kutnjak, D. Miljenović, and A. Mirković, "Improving competitiveness of small and medium-sized enterprises with the application of quality management system," *Sci. J. Marit. Res.*, vol. 33, no. 1, pp. 11–21, 2019, doi: 10.31217/p.33.1.2.
[28] J. V. Gray, G. Anand, and A. V. Roth, "The influence of ISO 9000 certification on process compliance," *Prod. Oper. Manage.*, vol. 24, no. 3, pp. 369–382, Mar. 2015, doi: 10.1111/poms.12252.
[29] Z. Zhu, "A comparison of quality programmes: Total quality management and ISO 9000," *Total Qual. Manage.*, vol. 10, no. 2, pp. 291–297, Mar. 1999, doi: 10.1080/0954412998018.
[30] K. D. Gotzamani, G. D. Tsiotras, M. Nicolaou, A. Nicolaides, and V. Hadjiadamou, "The contribution to excellence of ISO 9001: The case of certified organisations in cyprus," *TQM Mag.*, vol. 19, no. 5, pp. 388–402, Aug. 2007, doi: 10.1108/09544780710817838.
[31] J. Anttila and K. Jussila, "ISO 9001:2015–a questionable reform. What should the implementing organisations understand and do?" *Total Qual. Manag. Bus. Excell.*, vol. 28, nos. 9–10, pp. 1090–1105, 2017, doi: 10.1080/14783363.2017.1309119.
[32] Y. K. Chan, J. Kam, K. Neailey, and W. H. Ip, "How IMS can achieve ISO 9001:2000 certification," *TQM Mag.*, vol. 14, no. 6, pp. 345–349, 2002, doi: 10.1108/09544780210447447.
[33] Y. Du, J. Yin, and Y. Zhang, "How innovativeness and institution affect ISO 9000 adoption and its effectiveness: Evidence from small and medium enterprises in China," *Total Qual. Manage. Bus. Excellence*, vol. 27, nos. 11–12, pp. 1315–1331, Nov. 2016, doi: 10.1080/14783363.2015.1075874.
[34] J. J. Tarí, "Components of successful total quality management," *TQM Mag.*, vol. 17, no. 2, pp. 182–194, Apr. 2005, doi: 10.1108/09544780510583245.
[35] C. Escanciano and F. J. Iglesias-Rodríguez, "Quality management and integrated total quality in Spanish mining: Results of an empirical study," *DYNA*, vol. 79, no. 171, pp. 167–174, 2012.
[36] S. A. Oke and O. E. Owaba-Charles, "Implementation of ISO-based quality management systems: A review of the literature," *Int. J. Product. Qual. Manag.*, vol. 2, no. 1, pp. 81–111, 2007, doi: 10.1504/IJPQM.2007.011469.
[37] P. Kumar, J. Maiti, and A. Gunasekaran, "Impact of quality management systems on firm performance," *Int. J. Qual. Rel. Manage.*, vol. 35, no. 5, pp. 1034–1059, May 2018, doi: 10.1108/ijqrm-02-2017-0030.
[38] M. Feng, M. Terziovski, and D. Samson, "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.*, vol. 19, no. 1, pp. 22–37, 2008, doi: 10.1108/17410380810843435.
[39] K. Ruamchat, N. Thawesaengskulthai, and C. Pongpanich, "Development of quality management system under ISO 9001:2015 and Joint Inspection Group (JIG) for aviation fuelling service," *Manag. Prod. Eng. Rev.*, vol. 8, no. 3, pp. 50–59, 2017, doi: 10.1515/mper-2017-0028.
[40] A. E. Wilcock and K. A. Boys, "Improving quality management: ISO 9001 benefits for agrifood firms," *J. Agribusiness Developing Emerg. Econ.*, vol. 7, no. 1, pp. 1–37, 2017, doi: 10.1108/JADEE-12-2014-0046.
[41] M. Kumar and J. Antony, "Comparing the quality management practices in UK SMEs," *Ind. Manage. Data Syst.*, vol. 108, no. 9, pp. 1153–1166, Oct. 2008, doi: 10.1108/02635570810914865.
[42] P. Rogala, "Identification of barriers to improving quality management systems: The management representatives ' perspective,'" *TQM J.*, vol. 28, no. 1, pp. 79–88, Jan. 2016, doi: 10.1108/TQM-05-2014-0047.
[43] G. Santos, M. Rebelo, N. Lopes, M. R. Alves, and R. Silva, "Implementing and certifying ISO 14001 in portugal: Motives, difficulties and benefits after ISO 9001 certification," *Total Qual. Manage. Bus. Excellence*, vol. 27, nos. 11–12, pp. 1211–1223, Nov. 2016, doi: 10.1080/14783363.2015.1065176.
[44] E. Sfakianaki and A. P. Kakouris, "Obstacles to ISO 9001 certification in SMEs," *Total Qual. Manag. Bus. Excell.*, vol. 31, nos. 13–14, pp. 1544–1564, 2018, doi: 10.1080/14783363.2018.1490640.
[45] B. Brotherton and J. Shaw, "Towards an identification and classification of critical success factors in UK hotels Plc," *Int. J. Hospitality Manag.*, vol. 15, no. 2, pp. 113–135, 1996, doi: 10.1016/0278-4319(96)00014-X.
[46] R. B. Coronado and J. Antony, "Critical success factors for the successful implementation of six sigma projects in organisations," *TQM Mag.*, vol. 14, no. 2, pp. 92–99, Apr. 2002, doi: 10.1108/09544780210416702.
[47] K. Jeyaraman and L. Kee Teo, "A conceptual framework for critical success factors of lean six sigma: Implementation on the performance of electronic manufacturing service industry," *Int. J. Lean Six Sigma*, vol. 1, no. 3, pp. 191–215, Aug. 2010, doi: 10.1108/20401461011075008.
[48] M. Lande, R. L. Shrivastava, and D. Seth, "Critical success factors for lean six sigma in SMEs (small and medium enterprises)," *TQM J.*, vol. 28, no. 4, pp. 613–635, Jun. 2016, doi: 10.1108/TQM-12-2014-0107.
[49] M. Kumar, J. Antony, and A. Douglas, "Does size matter for six sigma implementation?" *TQM J.*, vol. 21, no. 6, pp. 623–635, Oct. 2009, doi: 10.1108/17542730910995882.
[50] D. Aggelogiannopoulos, E. H. Drosinos, and P. Athanasopoulos, "Implementation of a quality management system (QMS) according to the ISO 9000 family in a Greek small-sized winery: A case study," *Food Control*, vol. 18, no. 9, pp. 1077–1085, Sep. 2007, doi: 10.1016/j.foodcont.2006.07.010.
[51] J. Anttila and K. Jussila, "Understanding quality–conceptualization of the fundamental concepts of quality," *Int. J. Qual. Service Sci.*, vol. 9, nos. 3–4, pp. 251–268, Sep. 2017, doi: 10.1108/IJQSS-03-2017-0020.
[52] S. Dowlatshahi and S. Hooshangi, "Enabling quality management systems in the maquiladoras: An empirical analysis," *Int. J. Qual. Rel. Manage.*, vol. 27, no. 9, pp. 981–1001, Oct. 2010, doi: 10.1108/02656711011084792.
[53] C. Militaru and A. Zanfir, "The vision of new ISO 9000: 2015 standards," *Knowl. Horizons-Econ.*, vol. 8, no. 1, pp. 131–135, 2016. [Online]. Available: http://conricyt3.summon.serialssolutions.com/#!/search?bookMark=ePnHCXMw42LgTQStzc4rAe_hSmFi4ASdGK4L6nqwgNmgJTrGRhzwgRBj8BnknAyaIR6uCmGeoDJEwd9Nwc81XMEz2F8BdKulFbCaMlUIDnH0c3EMcgnmZlB2cw1x9tCFlZ7x0IAvjgelN1NgujIBnTlJjCoA6-0uaQ
[54] C. V. Fotopoulos, E. L. Psomas, and F. K. Vouzas, "ISO 9001:2000 implementation in the Greek food sector," *TQM J.*, vol. 22, no. 2, pp. 129–142, 2010, doi: 10.1108/17542731011024255.
[55] H. A. Quazi and S. R. Padibjo, "A journey toward total quality management through ISO 9000 certification-a study on small- and medium-sized enterprises in Singapore," *Int. J. Qual. Rel. Manage.*, vol. 15, no. 5, pp. 489–508, Aug. 1998, doi: 10.1108/02656719810196225.
[56] M. Sıtkılkay and E. Aslan, "The effect of the ISO 9001 quality management system on the performance of SMEs," *Int. J. Qual. Rel. Manage.*, vol. 29, no. 7, pp. 753–778, Jul. 2012, doi: 10.1108/02656711211258517.
[57] E. Soltani and P. Lai, "Approaches to quality management in the UK: Survey evidence and implications," *Benchmarking, Int. J.*, vol. 14, no. 4, pp. 429–454, Jul. 2007, doi: 10.1108/14635770710761852.
[58] S. Sumaedi and M. Yarmen, "The effectiveness of ISO 9001 implementation in food manufacturing companies: A proposed measurement instrument," *Procedia Food Sci.*, vol. 3, pp. 436–444, 2015, doi: 10.1016/j.profoo.2015.01.048.

[59] H. Sun, "Total quality management, ISO 9000 certification and performance improvement," *Int. J. Qual. Rel. Manage.*, vol. 17, no. 2, pp. 168–179, Mar. 2000, doi: 10.1108/02656710010304573.

[60] J. P. Wilson and L. Campbell, "Developing a knowledge management policy for ISO 9001: 2015," *J. Knowl. Manag.*, vol. 20, no. 4, pp. 829–844, 2016, doi: 10.1108/JKM-11-2015-0472.

[61] Y. Li and H. Huang, "Validating the job satisfaction survey in voluntary child welfare," *Children Youth Services Rev.*, vol. 83, pp. 1–8, Dec. 2017, doi: 10.1016/j.childyouth.2017.10.020.

[62] M. Maciel-Monteon, J. Limon-Romero, C. Gastelum-Acosta, D. Tlapa, Y. Baez-Lopez, and H. A. Solano-Lamphar, "Measuring critical success factors for six sigma in higher education institutions: Development and validation of a surveying instrument," *IEEE Access*, vol. 8, pp. 1813–1823, 2020, doi: 10.1109/ACCESS.2019.2962521.

[63] K. Sagherian, L. M. Steege, J. Geiger-Brown, and D. Harrington, "The nursing performance instrument: Exploratory and confirmatory factor analyses in registered nurses," *J. Nurs. Res.*, vol. 26, no. 2, pp. 130–137, 2017.

[64] D. P. Kafetzopoulos and K. D. Gotzamani, "Critical factors, food quality management and organizational performance," *Food Control*, vol. 40, pp. 1–11, Jun. 2014, doi: 10.1016/j.foodcont.2013.11.029.

[65] M. T. M. Rubio and V. R. Arias, "Study of the main motivations and discouraging factors for the implementation of ISO 9000 standards in Spanish agribusiness sector," *J. Int. Food Agribus. Mark.*, vol. 17, no. 2, pp. 213–227, 2005, doi: 10.1300/J047v17n02_12.

[66] N. A. Alsaleh, "Application of quality tools by the Saudi food industry," *TQM Mag.*, vol. 19, no. 2, pp. 150–161, Mar. 2007, doi: 10.1108/09544780710729999.

[67] P. J. Singh and A. Smith, "An empirically validated quality management measurement instrument," *Benchmarking, Int. J.*, vol. 13, no. 4, pp. 493–522, Jul. 2006, doi: 10.1108/14635770610676317.

[68] C. R. Turner, G. F. Ortmann, and M. C. Lyne, "Adoption of ISO 9000 quality assurance standards by South African agribusiness firms," *Agribusiness, Int. J.*, vol. 16, no. 3, pp. 295–307, 2000, doi: 10.1002/1520-6297(200022)16:3<295::AID-AGR3>3.0.CO;2-P.

[69] J. F. J. Hair, W. C. Black, B. J. Babin, and R. E. Anderson, *Multivariate Data Analysis*, 7th ed. London, U.K.: Pearson, 2009.

[70] R. B. Kline, "Principles and practices of structural equation modeling," in *Methodology in the Social Sciences*, 2nd ed. London, U.K.: Guildford Press, 2005, p. 356.

[71] B. M. Byrne, *Structural Equation Modeling With AMOS*, 2nd ed. New York, NY, USA: Taylor & Francis, 2013.

[72] S. Macias-Velasquez, Y. Baez-Lopez, A. A. Maldonado-Macías, J. Limon-Romero, and D. Tlapa, "Burnout syndrome in middle and senior management in the industrial manufacturing sector of Mexico," *Int. J. Environ. Res. Public Health*, vol. 16, no. 8, p. 1467, Apr. 2019, doi: 10.3390/ijerph16081467.

[73] J. M. Rodríguez-Mantilla, M. J. Fernández-Díaz, and V. L. Carrascosa, "Validation of a questionnaire to evaluate the impact of ISO 9001 standards in schools with a confirmatory factor analysis," *Stud. Educ. Eval.*, vol. 62, pp. 37–48, Sep. 2019, doi: 10.1016/j.stueduc.2019.03.013.

[74] M. S. Khine, *Applications of Structural Equation Modeling in Educational Research and Practice*. Rotterdam, The Netherlands: Sense Publishers, 2014.

[75] E. Psomas and A. Pantouvakis, "ISO 9001 overall performance dimensions: An exploratory study," *TQM J.*, vol. 27, no. 5, pp. 519–531, Aug. 2015, doi: 10.1108/TQM-04-2014-0037.

[76] J. Xiong, Z. He, B. Ke, and M. Zhang, "Development and validation of a measurement instrument for assessing quality management practices in hospitals: An exploratory study," *Total Qual. Manage. Bus. Excellence*, vol. 27, nos. 5–6, pp. 465–478, May 2016, doi: 10.1080/14783363.2015.1012059.

[77] D. K. W. Young, P. Y. N. Ng, J. Pan, T. Fung, and D. Cheng, "Validity and reliability of recovery assessment scale for cantonese speaking Chinese consumers with mental illness," *Int. J. Mental Health Addiction*, vol. 15, no. 1, pp. 198–208, Feb. 2017, doi: 10.1007/s11469-016-9657-3.

[78] D. Tlapa, J. Limon, J. L. García-Alcaraz, Y. Baez, and C. Sánchez, "Six sigma enablers in mexican manufacturing companies: A proposed model," *Ind. Manage. Data Syst.*, vol. 116, no. 5, pp. 926–959, Jun. 2016, doi: 10.1108/IMDS-06-2015-0265.

[79] C. Valmohammadi and M. Kalantari, "The moderating effect of motivations on the relationship between obtaining ISO 9001 certification and organizational performance," *TQM J.*, vol. 27, no. 5, pp. 503–518, Aug. 2015, doi: 10.1108/tqm-05-2014-0042.

[80] A. Bastas and K. Liyanage, "ISO 9001 and supply chain integration principles based sustainable development: A delphi study," *Sustainability*, vol. 10, no. 12, p. 4569, Dec. 2018, doi: 10.3390/su10124569.

[81] D. George and P. Mallery, *SPSS for Windows Step by Step: A Simple Guide for Reference 11.0 Update*, 4th ed. Boston, MA, USA: Ally & Bacon, 2013.

[82] S. Sharma, S. Mukherjee, A. Kumar, and W. R. Dillon, "A simulation study to investigate the use of cutoff values for assessing model fit in covariance structure models," *J. Bus. Res.*, vol. 58, no. 7, pp. 935–943, Jul. 2005, doi: 10.1016/j.jbusres.2003.10.007.

[83] A. Armawati, R. Syamwil, and T. S. Florentinus, "Implementation of quality management system ISO 9001:2015 integrated with accreditation standards in SMK 1 sragi," *J. Vocational Career Edu.*, vol. 3, no. 2, p. 2015, Dec. 2018, doi: 10.15294/jvce.v3i2.16179.

[84] I. I. Doronina, V. N. Borobov, E. A. Ivanova, E. V. Gorynya, and B. M. Zhukov, "Agro-industrial clusters as a factor of increasing competitiveness of the region," *Int. J. Econ. Financ. Issues*, vol. 6, no. 1, pp. 295–299, 2016. [Online]. Available: https://www.scopus.com/inward/record.uri?eid=2-s2.0-84979842427&partnerID=40&md5=0b1adaafe2c3c52881b6409f2a3b363c

[85] B. Poksinska, J. A. E. Eklund, and J. J. Dahlgaard, "ISO 9001:2000 in small organisations: Lost opportunities, benefits and influencing factors," *Int. J. Qual. Reliab. Manag.*, vol. 23, no. 5, pp. 490–512, 2006, doi: 10.1108/02656710610664578.

[86] D. Almeida, N. Pradhan, and J. J. Muniz, "Assessment of ISO 9001:2015 implementation factors based on AHP: Case study in Brazilian automotive sector," *Int. J. Qual. Reliab. Manag.*, vol. 34, no. 1, pp. 231–250, 2018, doi: 10.1108/IJQRM-12-2016-0228.

[87] S. R. Lobo, P. Samaranayake, and T. Laosirihongthong, "Quality management capabilities of manufacturing industries in the western Sydney region: Comparative analysis for quality improvement," *Int. J. Qual. Rel. Manage.*, vol. 35, no. 6, pp. 1232–1252, Jun. 2018.

[88] R. Brajer-Marczak, "Employee engagement in continuous improvement of processes," *Management*, vol. 18, no. 2, pp. 88–103, Dec. 2014, doi: 10.2478/manment-2014-0044.

[89] E. Lundmark and A. Westelius, "Effects of quality management according to ISO 9000: A Swedish study of the transit to ISO 9000:2000," *Total Qual. Manag. Bus. Excell.*, vol. 17, no. 8, pp. 1021–1042, 2006, doi: 10.1080/14783360600748000.

[90] J. T. Quirós and M. D. R. F. Justino, "A comparative analysis between certified and non-certified companies through the quality management system," *Int. J. Qual. Rel. Manage.*, vol. 30, no. 9, pp. 958–969, Oct. 2013, doi: 10.1108/IJQRM-04-2011-0059.

[91] S. Dellana and J. Kros, "ISO 9001 and supply chain quality in the USA," *Int. J. Productiv. Perform. Manage.*, vol. 67, no. 2, pp. 297–317, Feb. 2018, doi: 10.1108/IJPPM-05-2015-0080.

[92] S. Jasarevic, M. Diering, M. Hadzistevic, and F. Plevjkak, "Influence of introduction time, size and activity of organization to the achieved effects of introduced quality system," *Int. J. Eng.*, vol. 10, no. 2, pp. 21–30, 2012.

[93] X. Zu, T. L. Robbins, and L. D. Fredendall, "Mapping the critical links between organizational culture and TQM/six sigma practices," *Int. J. Prod. Econ.*, vol. 123, no. 1, pp. 86–106, Jan. 2010, doi: 10.1016/j.ijpe.2009.07.009.

[94] K.-B. Ooi, "TQM practices and knowledge management: A multi-group analysis of constructs and structural invariance between the manufacturing and service sectors," *Total Qual. Manage. Bus. Excellence*, vol. 26, nos. 11–12, pp. 1131–1145, Dec. 2015, doi: 10.1080/14783363.2014.914642.

[95] N. Hietschold, R. Reinhardt, and S. Gurtner, "Measuring critical success factors of TQM implementation successfully–a systematic literature review," *Int. J. Prod. Res.*, vol. 52, no. 21, pp. 6254–6272, Nov. 2014, doi: 10.1080/00207543.2014.918288.

[96] A. Shokri, T. S. Waring, and F. Nabhani, "Investigating the readiness of people in manufacturing SMEs to embark on lean six sigma projects," *Int. J. Oper. Prod. Manage.*, vol. 36, no. 8, pp. 850–878, Aug. 2016, doi: 10.1108/IJOPM-11-2014-0530.

MARCOS ALBERTO SANCHEZ-LIZARRAGA received the B.S. degree in industrial engineering from the Autonomous University of Occident, Sinaloa, México, in 2011, and the M.S. degree in industrial engineering from the Technological Institute of Los Mochis, México, in 2013. He is currently pursuing the Ph.D. degree in science with the Faculty of Engineering, Architecture, and Design, Universidad Autónoma de Baja California, México. 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 México.

JORGE LIMON-ROMERO received the B.S. degree in industrial engineering from the Technological Institute of Los Mochis, México, in 2001, the M.S. degree in industrial engineering from the Technological Institute of Hermosillo in 2004, and the Ph.D. degree from the Universidad Autónoma de Baja California (UABC), México, in 2013. He is currently a Professor of industrial engineering with the Faculty of Engineering, Architecture, and Design, UABC. He has participated in several research projects related to process improvement and authored or coauthored more than 30 journal articles, book chapters, and conference papers. His research interests include statistical modeling, multivariate data analysis, and 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 in México and the optimization of industrial processes network (ROPRIN).

DIEGO TLAPA received the B.S. degree in industrial engineering from the Technological Institute of Ciudad Juarez, México, in 2002, and the M.S. degree in industrial engineering and the Ph.D. degree from the Universidad Autónoma de Baja California (UABC), in 2007 and 2013, respectively. He is currently a Professor of Industrial Engineering with the School of Engineering, Architecture, and Design, UABC, México. He has participated in several research projects related to process improvement and authored or coauthored more than 30 journal articles, book chapters, and conference papers. His research interests include 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 in México and the optimization of industrial processes network (ROPRIN).

YOLANDA BAEZ-LOPEZ received the B.S. degree in industrial engineering from the Technological Institute of Los Mochis, México, in 2002, and the M.S. degree in industrial engineering and the Ph.D. degree from the Universidad Autónoma de Baja California (UABC), in 2008 and 2014, respectively. She is currently a Professor of Industrial Engineering with the Faculty of Engineering, Architecture, and Design, UABC. She has been the Coordinator of the Department of Vocational and university linkage at the Ensenada Campus. She has participated in several research projects related to process improvement and authored or coauthored more than 25 journal articles, book chapters, and conference papers. Her research interests include six sigma methodology, lean manufacturing, and human reliability. She is a member of the National System of Researchers of the National Council of Science and Technology in México.

CESAR PUENTE received the B.S. degree in computer engineering from the Universidad Autónoma de San Luis Potosí, México, in 2002, and the M.S. degree in computer science and the Ph.D. degree from the Ensenada Center for Scientific Research and Higher Education, in 2006 and 2011, respectively. He is currently a Professor of Computer Engineering with the Faculty of Engineering, Universidad Autónoma de San Luis Potosí. His research interests include evolutionary optimization algorithms applied to pattern recognition, computer vision and remote sensing, systems optimization, and statistical inference.

LIZBETH PUERTA-SIERRA received the Ph.D. degree in administrative sciences and the master's degree in administration from the Universidad Autónoma de Baja California (UABC). She is a Researcher and a full-time Professor with Universidad Anáhuac México, México. Her research interests include the university-industry collaboration, the management of technology transfer, and innovation ecosystems. She is a member of the National System of Researchers of the National Council of Science and Technology in México.

SINUE ONTIVEROS received the B.S. degree in industrial engineering from the Technological Institute of Los Mochis, Los Mochis, México, in 2003, the M.S. degree in industrial engineering from the Technological Institute of Hermosillo, Hermosillo, México, in 2007, and the Ph.D. degree in industrial engineering from the University of Zaragoza, Zaragoza, Spain, in 2013. He has authored or coauthored more than 40 articles. He is an active member of the National System of Researchers. His main research interests include computed tomography in metrology applications and quality control. He is an Associate Partner of the Manufacturing Engineering and Advanced Metrology Group, University of Zaragoza. Since 2014, he has been a full-time Professor–Researcher with the Universidad Autónoma de Baja California, Tecate, México.