An Exploratory Qualitative Study on the International Standards Organization Quality Certification in the Health Sciences

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ABSTRACT:

With the introduction of mandatory ISO certification within the in vitro diagnostic (IVD) industry in South Africa, especially the ISO 13485:2016 quality management system (QMS) for medical devices, it is unclear what contribution ISO certification makes to the South African IVD medical device industry. Moreover, the impact of compulsory ISO certification on the IVD industry in South Africa is also not documented. Thus, this paper reports the findings from an exploratory qualitative study conducted among a probability sample of 10 senior managers of IVD companies. It became evident that most of the participants supported the use of the ISO 9001 certification standard and some companies were certified for up to 10 years. The companies' leadership also supported iso certification and adopted this quality management system. It was also ascertained that the participants perceived the adoption of the ISO quality management system positively impacted their organizations' performance since customers have greater confidence in the products and the companies. It is recommended that the Invitro company leadership embrace ISO as a quality management system and ensure that they retain certification since it will impact their performance and enhance customer perceptions of the service and quality.

1. Introduction

The Food and Drug Administration (FDA) defines in vitro diagnostic (IVD) products "as reagents, instruments, and systems intended for use in the diagnosis of diseases or other conditions to cure, mitigate, treat or prevent disease. Specimens taken from the human body are tested on IVD products," (U.S Food & Drug Administration, 2019). Previously, in the absence of a regulatory authority in South Africa, the medical industry relied on the National Health Laboratory Service (NHLS) to provide advice and guidance on IVD products. This, however, changed in 2014 when the Medicines Control Council (MCC) included IVDs in preparation for the creation of the South African Health Products Regulatory Authority (SAHPRA) which was established in February 2018 (Keyter, et al., 2018). SAHPRA ensures that "medicines, medical devices, and IVDs meet the mandatory standards to safeguard the health and well-being of South Africans."

The Southern African Laboratory Diagnostic Association (SALDA) which is a collaboration of multinational and local companies that distribute IVD tests, comprises "54 local and multinational IVD companies, responsible for manufacturing, importing, selling, servicing, marketing and distributing of IVD products in South Africa," (SALDA, 2022).

Due to the complexity and uniqueness of health services, health service providers have taken longer than other industries to adopt and accept quality management systems (Sedevich-Fons, 2014). ISO 9001 certifications are becoming more popular in the healthcare industry and interest increased since 2008 (Bretana & Alvarez, 2017). The reason behind this is that "ISO 9001 certification and hospital accreditation are essential instruments to improve the overall quality of the health service."

Johannesen and Wigg (2017) argue that "ISO 9001 is widely used in the healthcare sector but they question the assumed benefits since the adoption of internal control systems has shown to be a challenging task in healthcare since the systems are not built around the fulfillment of

regulatory requirements." Rakhmawati, et al., (2014) agree with this statement and assert that "there are inconclusive findings in research regarding the effectiveness of ISO 9001 implementation in the healthcare service sector."

It is therefore unclear what contribution ISO certification makes to the South African IVD medical device industry and customers' perceptions regarding ISO-certified and non-certified companies. Moreover, the impact of compulsory ISO certification on the IVD industry in South Africa is also not well documented. With the mandatory implementation of a quality management system (QMS) within each IVD company, this exploratory qualitative research will critically evaluate ISO certification in the IVD Industry in South Africa. A qualitative study was conducted to assess customer service, operational performance, quality of IVD products, competitive advantage, and benefits obtained from ISO certification.

2. Literature Review

The International Organisation for Standardization (ISO) is an independent, non-governmental international organization with a membership of 165 national standards bodies with one member per country. There are 23,301 International Standards that cover all aspects of manufacturing and technology (ISO, 2019). ISO is a network of national standard bodies (NSB) and ISO standards are developed by technical committees (TC) that consist of groups of experts (Hoyle, 2018). The standards range from quality management systems, measurement management systems, guidance documents, environmental management systems, compliance management systems, codes, formats, medical devices, food safety management, social responsibility, risk management, occupational health to anti-bribery and corruption management systems.

The core standards of the ISO 9000 family consist of ISO 9000, ISO 9001, ISO 9004 and ISO 19011 (ISO, 2015). This research will focus on the ISO 9001:2015 and ISO 13485:2016 standards. The ISO 9001 international standard specifies "the requirements aimed primarily at providing confidence in the service and products provided by a company and thereby enhancing customer satisfaction." The ISO 9001 standard outlines "the compliance requirements and steps for adopting and implementing a methodical QMS."

After the implementation of the QMS, auditing and certification follow (Gokpinar, et al., 2019). An important part of the ISO 9001 QMS implementation is "to establish a performance monitoring, measurement and analysis framework in order to identify the performance levels achieved and to decide whether these achievements are satisfactory," (Gokpinar, et al., 2019).

With the implementation of ISO 9001:2015, "applicability expanded to when a company seeks to create a new market for their product and when a company seeks opportunities to develop new products in their chosen markets," (Hoyle, 2018). ISO 9001:2015 assists a company "to identify new business opportunities, working more efficiently and expanding into new markets as some customers require ISO 9001 as a prerequisite for doing business," (ISO, 2015).

The South African Department of Health (DOH) published an update on regulations related to in vitro diagnostic (IVD) medical devices in the Government Gazette number 40480. The DOH stated that "companies must provide the Council with evidence of certification to a QMS for medical devices and IVDs, which means that all IVD companies must obtain ISO certification."

Leadership and Quality Management

Although leaders are responsible for the effectiveness of the QMS, a perpetual complaint from quality professionals has been that "they experience a challenge in communicating with top management," (West & Cianfrani, 2016). Thus, one of the barriers to implementing a QMS is "the lack of support from leadership," (Abd-Elwahed & El-Baz, 2018).

According to Mosadeghrad (2015), there is "a strong relationship between leadership and the success of total quality management since it relies on a manager's ability to create a vision and plan to drive organisational change to obtain quality management success." Mosadeghrad (2015) further states that "leaders and managers must personally be involved in developing and implementing quality management change and support continuous improvement."

The ISO 9001: 2015 standards specify actions to demonstrate the leadership and commitment of top management and its stated that "top management shall demonstrate leadership and commitment to the quality management systems by taking accountability for the

effectiveness of the quality management systems, ensuring resources, promoting the use of the process approach and risk-based thinking, communication the importance of effective quality management, promoting improvement and ensuring the quality management system requirements achieves its intended results," (ISO, 2015).

Reid (2020) argues that with regard to ISO 13485:2016, "top management must be committed towards the formation and implementation of the QMS. Top management must communicate the importance of customer and regulatory requirements to the entire company, establish a quality policy, make sure the quality objectives are established and conduct management reviews. Top management must also provide the necessary resources required," (Reid , 2020).

ISO Adoption and Customer Satisfaction

According to Nurcahyo and Habiburrahman (2020), "all the ISO variables (leadership, customer requirements, defect prevention, continuous improvement, and supplier management) have a positive impact on operational performance which leads to improved customer satisfaction." According to (Ganapavarapu & Prathigadapa, 2015), "quality management always deals with customer satisfaction and since customers are important stakeholders, their satisfaction should be a priority for all companies," (Jeske, et al., 2015). Customer satisfaction is "a measure of how services and products meet customer expectations and customer satisfaction is considerably affected by service delivery and unhappy customers lead to reduced sales or loss of business," (Rakhmawati, et al., 2014).

In the healthcare industry, customer satisfaction is very important to determine the success of service companies. According to Arsita and Idris (2019), "one way to be sustainable in the healthcare industry is to create customer satisfaction through improved service quality."

In 2012, a literature review examined 82 empirical studies related to ISO 9000 and based on the review it was concluded that "ISO 9000 improves customer satisfaction," (Tari, et al., 2012). The review also concluded that "ISO 9000 certification enhances the image of the company, which contributes to the perception of better customer service."

Some researchers used service quality as a performance measure to conduct research in the healthcare industry and concluded that "higher service quality does not guarantee higher customer satisfaction," (Rakhmawati, et al., 2014). On the other hand, Chatzoglou, et al., (2015) found that "there is a statistically significant relationship between ISO certification and customer satisfaction."

Quality management, competitive advantage and organizational performance

The relationship between quality management and competitive advantage is somewhat conflicting (Yeng, et al., 2018), since some studies established a positive relationship between quality management and customer satisfaction, which improved company image and created a competitive advantage, while other studies revealed that the direct relationship between quality management and competitive advantage is very vague (Yeng, et al., 2018).

From a financial perspective, the literature suggests that "ISO certification has a positive influence on the financial performance of a company," (Ochieng, et al., 2015). Ochieng et al. (2015) reported that "ISO certification influences the return on net assets of a company and, in turn, company performance." Psomas and Pantouvakis (2015) concur since they considered operational, market and financial measures as performance indicators and found that the performance increased since ISO certification.

Little information is currently available on why some South African IVD companies are ISO-certified and others are not. It is also unclear what contribution ISO certification makes to the South Africa IVD medical device industry, and customers' perceptions regarding ISO-certified and non-certified companies. Moreover, the impact of compulsory ISO certification on the IVD industry in South Africa is also not documented.

It is against the above background and the literature reviewed that this study will explore the impact of mandatory implementation of a QMS by the IVD industry in South Africa.

3. Research Methodology

Considering the aim of the study, a qualitative approach was adopted, since qualitative research aims to "provide an in-depth and interpreted view of the social world by

learning about the research participants' social and material settings, perceptions, attitudes, and backgrounds," (van der Walt, 2017). Furthermore, in qualitative research, "the researcher has the opportunity to probe and clarify their responses," (van der Walt, 2017).

All 2725 employees of 54 South African IVD companies that are members of the South African Laboratory Diagnostic Association (SALDA) made up the target population for this study (SALDA, 2022). Deliberate or purposive sampling which entailed "selecting individuals with subject-matter expertise," was used (Creswell & Creswell, 2017). Senior management and quality managers of the IVD companies were interviewed, with each interview lasting between 10 to 20 minutes. A total of 8 semi-structured interviews were conducted with senior management and quality managers of the target population.

Since the aim of the study was to ascertain how ISO certification had affected organizational performance, the focus was on management commitment, adoption of ISO certification, product quality performance, customer service satisfaction focus, and organizational performance. The following objectives guided the interviews:

➢ To determine whether the IVD industry needs ISO certification.
➢ To determine whether there is a connection between customer service and IVD product ISO certification.
➢ To determine if IVD product quality is guaranteed by ISO certification.
➢ To assess the main advantages of ISO certification for businesses.
➢ To evaluate the relationship between organizational performance and ISO certification

Colleagues with different management backgrounds, professional experience, and educational backgrounds helped with the design and evaluation of the research instrument.

Each participant received an introductory letter outlining the aim of the study and what they were expected to contribute. All interviews were scheduled with the informed participants at a time that was convenient for both the researcher and the participant. All interviews were conducted by the researcher himself.

In order to perform the data analysis, the first step of the process involved importing all of the transcriptions from the individual interviews into NVivo as a single hermeneutic unit.

The demographic data of the participants enabled the researchers to move away from an "absolutism" perspective, which holds that "the phenomena of interest are the same regardless of work experience, and education, and towards a "universalism" perspective, which acknowledges that there may be universal psychological perspective."

The researcher read each individual transcript carefully to search for and identify codes leading to themes and subthemes and used a "concept-driven" approach to data coding, which involved "looking for concepts/ideas in the text, based on a careful reading of the data collected and writing down which patterns or themes observed. This included identifying multiple passages of the text that share the same code," (Gibbs, 2018).

To minimize researcher bias, the same questions were asked to all participants, allowing the researcher to "bracket" his own views throughout the research and enabling the researcher to code the data in a meaningful manner. The NVivo software acted as a storage device, since it holds all the records, codes, and findings in a single environment from the same research project, allowing the researcher to monitor, extract, compare, and explore the data inside the text that is meaningful to the research. Tajuddin and Jauhar (2015) believe that "the use of NVivo considerably increases the rigour and reliability of qualitative investigations."

Given that the research methodology was qualitative, the strategy used to build credibility, transferability, and dependability was based on the suggestions made by Moser and Korstjens (2018).

4. Research Findings

A word cloud was constructed to determine the pattern of text used in relation to the company quality information and the most meaningful words used included "ISO", "quality", "knowledge", "training", "familiar", and "requirement", among others. This is as illustrated in Figure 1.

Figure 1: Word cloud on company information

The text was then contextualised and sub-themes that emerged included structure, size, familiarity, duration, standard, and certification. The size of the participating organizations measured by the number of employees, is illustrated in Table 1.

Table1: Size of the company

Participants 1, 3, 5, and 7 indicated that they employed between 51 and 100 employees, whilst Participants 2, 4, and 8 indicated that they employed less than 50 employees. The largest company was that of Participant 6, reportedly employing between 101 and 300 employees. This shows that insights were obtained from Participants working for companies of different sizes.

The structure of the QA department within the participating companies is reflected in Table 2. The responses captured in Table 2 could be interpreted as a variation in the structure of the QA departments across the different companies. For example, Participant 3 points out that it is a "one person" company, whilst Participant 6 indicates that "each division has its own QA team".

Table 2: Responses for Structure of QA Department

Participant Number		Response
	1	We have a quality manager & 2C3:C10 other staff trained on ISO as backup
	2	We recently employed a quality member to implement ISO for us
	3	One person in Company
	4	No QA department
	5	One quality manager in company.
	6	Each division have its own QA team. 7 people.
	7	1 quality manager. For all 3 offices.
	8	One person doing all quality.

Whilst many organisations seek to attain the benefits of ISO certification, the results in Table 3 reveal that company 4 and company 2 do not have any form of certification. This pattern of results is consistent with the literature in that there are firms that attribute their economic performance to ISO certification, whilst other firms do not. As such, for some firms, ISO certification is a voluntary activity without any benefits (Cândido, et al., 2021), whilst for others it is mandatory for achieving economic benefits (Demir, et al., 2021).

There are different ISO standards, each with its own requirements. ISO 13485 provides guidance in the form of quality system regulations that are specific to the medical device industry (Speer, 2018). Within this context, participants were asked about the standards to which their companies are ISO certified.

Table 3: ISO Certification status of company

		Response
	1	Yes - ISO 9001:2015 & ISO 13485:2016
	2	No, but working on ISO 13485 to be implementation for 2023.
	3	Yes
Is company ISO certified?	**4**	No, not a requirement as our supplied are ISO 13485:2016 certified we are only distributors
	5	Yes
	6	Yes
	7	Yes
	8	Yes

The findings captured in Table 4 show that most of these companies are certified to the ISO 9001:2015 and ISO 13485:2016 standards. It was found that company 4 and 2 were not certified at all, whilst company 8 and 3 were ISO 9001:2015 certified. On the contrary, companies 7, 6, 5, and 1 were dually certified, with both ISO 9001:2015, and ISO 13485:2016 certification. This suggests that firms voluntarily adopted ISO 9001:2015 certification before ISO 13485:2016 became a mandatory requirement. However, studies in some countries reveal that ISO certification has become part of the regulatory framework, as in South Africa, and that companies have no choice but to work towards obtaining certification (Lopes, et al., 2019).

Table 4: ISO standards certification

Question	Participant	Response
	1	ISO 9001:2015 & ISO 13485:2016
	2	N/A
	3	ISO 9001:2015 (in process of ISO13485:2016 certification)
To which standard/s?	**4**	None
	5	ISO 9001:2015 & ISO 13485:2016
	6	ISO 9001:2015 & ISO 13485:2016
	7	ISO 9001:2015 & ISO 13485:2016
	8	ISO 9001:2015

Duration of ISO certification

The literature indicates that ISO certification needs to be renewed (Bravi, et al., 2019), since the certification is only valid for a period of three years (Cândido, et al., 2021). Thus, the participants were asked about the duration of their certification and the results are presented in Table 5. As shown in Table 5, Participating companies 1, 3, and 5 were certified for more than 10 years. This is interpreted as evidence to suggest that these companies have been renewing their certification, as highlighted by the literature (Cândido, et al., 2021). Participant 6 and 8 for 10 years and participant 8 reported 4 years, and again, interpreted as evidence to suggest that certification was renewed. These findings suggest that most of the participating firms actively engage with the ISO certification process, and comply with the

recommended renewal dates. This is particularly relevant to ISO 9001:2015 certification. With regards to ISO 13485:2016 certification, most of the Participating companies' certification is fairly new and has not reached the renewal stage. Company 4 and Company 2 reported that they were not certified.

Table 5: Duration of ISO certification

Question	Participant	Response
If Yes, how long have you been certified?	1	ISO 9001:2015 for over 10 years & we implemented ISO 13485:2016 last year (2021)
	2	N/A – we are not certified
	3	ISO 9001:2015 – more than 10 years (11 years). ISO 13485:2016 – In process to get certified
	4	N/A
	5	ISO 9001– more than 10 years. ISO 13485 – 1 year.
	6	ISO 9001– 10 years. ISO 13485 – None.
	7	ISO 9001– 10 years. ISO 13485 – 11 months.
	8	ISO 9001– 4 years.

Previous studies have found that the most common motivations to adopt ISO standards by organisations came from external pressures (Kakouris & Sfakianaki, 2019). These external pressures may include customer demand, participation in a tender system and market access. In this vein, participants were asked about their motivations for implementing ISO 13485:2016. A word cloud was constructed to determine the pattern of text used to explain the reasons that motivated ISO implementation. The key words include 'requirement', 'need', 'mandatory', 'SAHPRA', 'comply' and 'improvements', as illustrated in Figure 2.

Figure 2: Word cloud on ISO Certification

It is evident from Table 6 that all of the Participants, except Participant 4 reported that they opted for ISO certification because it was a SAHPRA requirement.

This implies that if regulations were not in place, then compliance with the ISO 13485:2016 standard would have been very minimal. These findings are consistent with what is been reported in the literature (Kakouris and Sfakianaki, 2019; Carrillo-Labella, et al., 2020).

Table 6: Motivation for ISO certification

Question	Participant	Response
What was the motivation to implement ISO 13485:2016?	1	We did not consider ISO 13485:2016 until SAHPRA made it mandatory for IVD companies in South Africa
	2	We will do it in 2023. We have to have ISO 13485 or close our doors thanks to SAHPRA.
	3	Because of SAHPRA requirement & to continue our business (regulatory requirement)
	4	We are not planning to implement as we are a distributor and it is not required
	5	Had to get certified to retain our SAHPRA licence. Regulatory requirement only.
	6	SAHPRA requirement only.
	7	Only because it is a regulatory requirement by SAHPRA (ISO 13485). ISO 9001:2015 – motivated by management to identify risks & process improvements.
	8	We are implementing it to comply to the SAHPRA requirement to continue to do business in Africa.

Some studies have indicated that ISO 9001 certification positively influenced a company's financial performance (Ochieng, et al., 2015), and the increase in financial performance due to ISO 9001 has been strongly validated in other studies (Psomas & Antony, 2015). However, many companies that lost their ISO certification saw no change in their financial performance based on the return on assets (ROA) and return on sales (ROS) that were used as the statistical measures at the time (Cândido, Carlos, et al., 2016).

A word cloud was developed to show the pattern of words used to talk about the cost of implementing ISO. It shows that the most common words included, "training", "audit", "compliance", "staff", "implementation", "administration", and "consultancy", as illustrated in Figure 3.
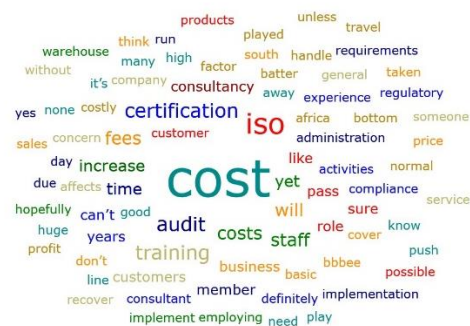
Figure 3: Word cloud for Cost

The text was then contextualised, and the sub-themes that emerged included implementation costs, cost and decision.

Customer Expectations

One of the main principles of ISO 9001 is the focus on customer service (ISO, 2015). According to Valmohammadi and Kalantari (2015), "ISO 9001 certified companies showed better levels of performance than non-certified companies," as the ISO 9001 quality management system requirements "helped to meet customers' requirements and demands," (Nabavi, et al., 2014). The intention has in most cases been to address the challenges that affect the quality of services. Thus, participants were asked about customer expectations from the implementation of ISO standards. A word cloud was also constructed under customer expectations to show the flow of words used to talk about the subject. The most commonly used words included 'better', 'processes', 'quality', 'management', 'increase', 'customer', 'services and 'performance', as illustrated in Figure 4.

Figure 4: Word cloud for customer expectations

The text was then contextualised, and the sub-themes that emerged included customer expectations, improvements as well as awareness.

Benefits of ISO implementation

One of the fundamental flaws with regards to quality in South Africa is registering with an ISO quality system merely to meet customer demands (Ramdass & Nemavhola, 2018). Obtaining certification may provide some benefits, like greater market share, but sadly other important principles of the quality system like process approach and evidence-based decision making are ignored. The findings in this regard captured in Table 7 reveal that Participants 1,6 and 3 reported that their customers get 'peace of mind' knowing that the provider focuses on service and product quality. Participant 8 reported risk management whilst 2 and 4 could not answer as they are not certified.

Wilcock and Boys (2017) found that "ISO 9001 certification offered a promising avenue to foster business development and business sustainability." Other benefits obtained from ISO 9001 certification were improvement of company image, access to tenders, access to new markets, compliance with legislation and an organised work environment (Santos, et al., 2016).

Table 7: Benefits of ISO implementation

Question	Participant	Response
What are the benefits of ISO certification to your customers?	1	They have peace of mind as we are focused on quality & that we have processes in place to support them consistently with good services & products.
	2	Can't answer that as we are not ISO certified.
	3	Service & product quality peace of mind
	4	Can't say as we are not certified
	5	High quality standard image.
	6	Pease of mind & trust. Quality of products. Business practices are up to date.
	7	Increase customer service & internal processes.
	8	ISO 9001 – Risk management. Better processes that leads to better customer service.

Awareness of ISO certification

Previous studies have found relatively low awareness level of the ISO certification and guidelines amongst customers (Aamer, et al., 2021), and some revealed inconsistency in their understanding of the purpose of

ISO certification (Sial , et al., 2021). It is apparent from Table 8 that the Participants' awareness of ISO certification is mixed, with some suggesting that ISO certification awareness was not important to customers. These mixed views are consisted with previous studies (Aamer, et al., 2021).

Table 8: Customer awareness of ISO status

Question	Participant	Response
Are your customers aware of your certification status?	1	Shows we are committed to quality & regulatory requirements.
	2	If it was important we would have done ISO in the past.
	3	Regulatory compliance
	4	I don't know
	5	ISO shows that there is a reputable quality standard in place.
	6	Quality image and products. Shows, stakeholders that you know what you are doing.
	7	Allow company to sell products. Signifies that we have sot procedures that are followed.
	8	In my opinion it is not important to them at all.

A word cloud was developed to show the pattern of text used in the section of general comments from the participants. Some of the word include, 'benefits', 'ISO',

'time', 'standards', 'consuming' and also 'good', as illustrated in Figure 5.

Figure 5: Word cloud for general comments

The Participants were also asked about their general comments about ISO certification and their responses are shown in Table 9.

Table 9: General comments

Question	Participant	Response
General comments with regards to ISO certification?	1	There is a need and if you implement for the right reasons, you will reap the benefits and rewards.
	2	Personally I think it is not required. We are forced to do something that the industry is not ready for.
	3	Many companies see ISO as a necessity while, they don't understand the standards & just want this certificates and don't live quality standards
	4	I did not know it is required (as we are only a distributor)
	5	Is time consuming. Audits takes time & is costly. Benefits of ISO 13485 not yet observed.
	6	Lots of admin. Love hate - as it is good but time consuming.
	7	It is a good thing and well needed – although very challenging. Not many certification bodies available.
	8	The benefits do not outweigh to cost or time to have ISO 13485.

The results show that there are mixed feelings towards ISO certification. Most of the Participants reported that it is essential, but challenging in terms of time consuming and hard to understand. Participant 8 reported how the benefits do not outweigh the cost or time to have ISO 13485 whilst Participant 4 did not even know it was required as they are only distributors.

5. Conclusions And Recommendations

The findings reveal that there are mixed views on whether there is a need for ISO certification in the IVD industry in South Africa. However, there are indications that ISO certification enhances customer service. Participants also share the view that that ISO certification is associated with the quality of IVD products. Further, there are also benefits that are derived from ISO certification, and these include positive perceptions about product quality, peace of mind derived from improved product quality, improved customer service, improved internal processes, and reduced perceived risk of product failure. Despite these benefits, there are some participants that had negative views on ISO certification. Yet, some participants shared the view that ISO certification drive change in organizational performance. These mixed results are of concern to ISO certification processes within South Africa. Hence, there is need to change negative perceptions about ISO certification, as well as to support companies with the necessary resources to ensure ISO certification.

It is recommended that the invitro company leadership embrace ISO as a QMS and ensure that they retain certification since it will impact their performance and enhance customer perceptions of the service and quality. However, a quantitative study should also be conducted to test relationships between the above variables and triangulate the data to confirm or refute the relations.

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