

Askari and Sohrabi (2017) state that the key benefit of organizations for implementing quality Management is the improvement of the link between the management system and innovation, which enhances processes and customer satisfaction. Ingason (2015) indicate that the large organization encounter less problems in implementing the system as then smaller organizations. In the same flow of thought, García et al (2016) indicate that many organizations that implements quality systems reports to have more positive and quantifiable outcome. There are many accounts that shows that the benefits of implementing quality management systems in organizations (Askari and Sohradi, 2017). Furthermore, Askari and Sohradi (2017) states deploying quality management system improve the organizational performance.

The ISO standard is a tool that formalizes activities in order accomplish product consistency based on the specification defined by the customer (Heras-Saizarbitoria and Boiral, 2013). It involves all parts of the organization, therefore it is felt throughout the organization, which improve the business processes and mostly importantly customer satisfaction (García, et al, 2016). Fabricio, et al, 2015 confirm this by stating that ISO is important to increase the organizations ability to satisfy its customers. However, Ingason (2015) argues that there is no evidence that demonstrates implementing ISO standards in an organization improves customer's satisfaction.

3. Methodology

3.1. Research Design

The research design that will be used is explanatory research. A correlational study was performed. The setting in which this study has been set is the normal setting of production. Data was collected under normal production environmental conditions without publicizing the data collection study to avoid biased data v]doo. The best research strategy that was found is meta-investigation. This sort of research technique is the mix of results from several studies the average impact of a similar intervention across studies (Cooper, et al., 2013). Meta-analysis works best for studies where something can be said about the course wherein the effect can be recognized. Observation (non -participant & covert), is the best data collection method for this study because there will be less influence from the researcher and a clear and concise overview of an issue is more achievable in this way. Participants are more likely to behave 'normally' if they aren't aware that they are being watched. The researcher is also less likely to influence the group.

3.2. Research Instrument, Data Collection and Analysis

A questionnaire containing structured questions with Likert-type scale was developed based on existing literature from a study by Rukaria (2014) who attempted to establish the relationship between ISO9001 and QMS certification and customer satisfaction in the Kenyan aviation industry. The authors questionnaire only targeted staff working for companies within the Kenyan aviation industry and did not target their customers. This is considered a limitation to that study, although the questionnaire used is relevant for this particular endeavour. To complement this limitation, the researchers involved in this current study adapted a questionnaire by Murmura and Bravi (2016) who attempted to obtain customers' wider vision on their QMS perception and establish how much they considered an organisation's quality important and whether a company being accredited is an important factor that determine their purchasing decisions.

The final questionnaire used in this study is divided into three sections. The first section targeted the socio-demographic data of respondents; the second section attempts to understand the company's customers; specifically, questions with regards to how the knowledge of ISO accreditation of the company they deal with affect their perception of quality of services and products they receive from the company in question. This particular line of questioning is based on the conclusion made from the findings by Dick, Gallimore and Brown (2002) which indicate that an organisation's accreditation to an ISO standard can make a profound difference on the way quality is perceived and measured in large service firms. Although, the study cited earlier is related to the service industry, it is important to assess this perception from a manufacturing perspective within a South African environment. Relevant to this study are the three questions posed to the customers, namely: Question 1 – Do you think that ISO accredited companies provide better services than companies that are not ISO accredited; Question 2 – In your opinion, do you think that the current services offered by this company can improve and Question 3 – Would you continue giving business to your current provider if the status quo (processes and services) remained the same? Lastly, the last section targeted the local diagnostics tools manufacturer's staff. The questions that needed the attention staff who took part to the study

were namely: Question 4: Do you know if your customers are currently happy with the services you provide? Question 5: In your own opinion do you think implementation Quality Management Systems improves customer satisfaction? And lastly, Question 6: If management chooses to implement a new version of ISO 13485 would you support it?

Primary data was collected from respondents who were identified within the company (staff) and through a list of the company's regular customers. This particular aspect regarding the study's approach to data collection is an important one, as the study's research tool targeted both customers and employees of the local manufacturer. The study used the questionnaire previously mentioned to collect primary data which was accompanied by an introductory letter addressing the confidentiality as well as instructions on how to complete it.

The questionnaire provided data that was analysed using SPSS 23.0 program to assess the Mean, Standard Deviation and Variance in order to evaluate the responses provided by the respondents. It is important to indicate that a 5-point Likert scale was used to determine these values (1 = strongly disagree; 2 = disagree; 3 = neither agree or disagree, 4 = agree; 5 = strongly agree).

4. Results and Discussions

This section presents the findings from the questionnaires distributed to the customers of this local diagnostics tools manufacturing company, then findings from its employees, and lastly, it provides a discussion based on the findings. However, the first section presents a description of the respondents categorised as staff and customers.

4.1. Description of Study Sample

The sample used in this study was divided into two categories: staff and customers. The sample of the study under the staff category is aged mainly between 21 and 55. The level of education of this category is shown in Table 1 below together with their level of experience. Majority of staff who responded to the questionnaire are in possession of a three-year university or college degree and have been with the company for more than 3 years and less than 10 years. The second category of respondents is constituted of customers. It is important to indicate that this category is made up of companies that purchase products and/or services from the local manufacturing company, and it has been assessed in terms of the types of products/services purchased from the local manufacturer and in terms of the number of years they have been interacting with the local manufacturing company. Worthy of note is that the local manufacturing company's customers that took part to the survey have been in business with the local manufacturer for more than five years as shown in Table 1.

Table 1. Sample Composition

Staff			Customers		
Level of education	<i>f</i>	%	Products/Services/Both	<i>f</i>	%
Matric	12	44.44%	Products	12	25.53%
National Diploma	13	48.15%	Services	17	36.17%
Postgraduate	2	7.41%	Both	18	38.30%
TOTAL			TOTAL		
Years of experience	<i>f</i>	%	Years of business with the local manufacturing company	<i>f</i>	%
≤ 3 Years	6	22.22%	≤ 1 Year	14	29.79%
> 3 and ≤ 10 Years	17	62.96%	> 1 and ≤ 5 Years	9	19.15%
> 10 Years	4	14.81%	> 5 Years	24	51.06%
TOTAL		100%	TOTAL		

4.2 Customers Responses

Responses to Question 1 – Do You think ISO accredited companies provides better services than that of companies that are not ISO accredited?

As depicted in the figure below, all the respondents are of the view that companies that are ISO accredited would usually provide better services than those that are not. The respondents' responses are shared equally with 50% strongly agreeing and the other 50% agreeing with the statement in Question 1.

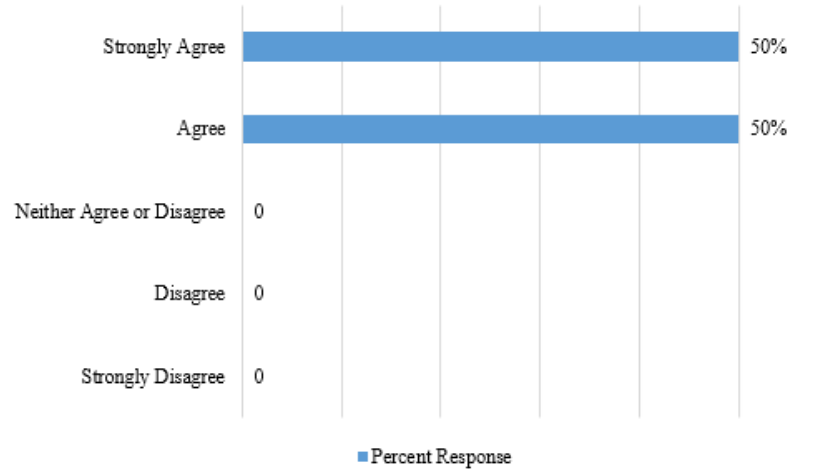


Figure 2. Question 1 – Percentage Responses

Responses to Question 2 – Do you think the current services offered at the local company should be improved?

The figure depicted below shows that majority of respondents or 75% of respondents agree that the services at the local company can be should be improved. 50% and 25% of the respondents strongly agree and agree respectively when asked whether the services at the local company should be improved, while 25% disagree.

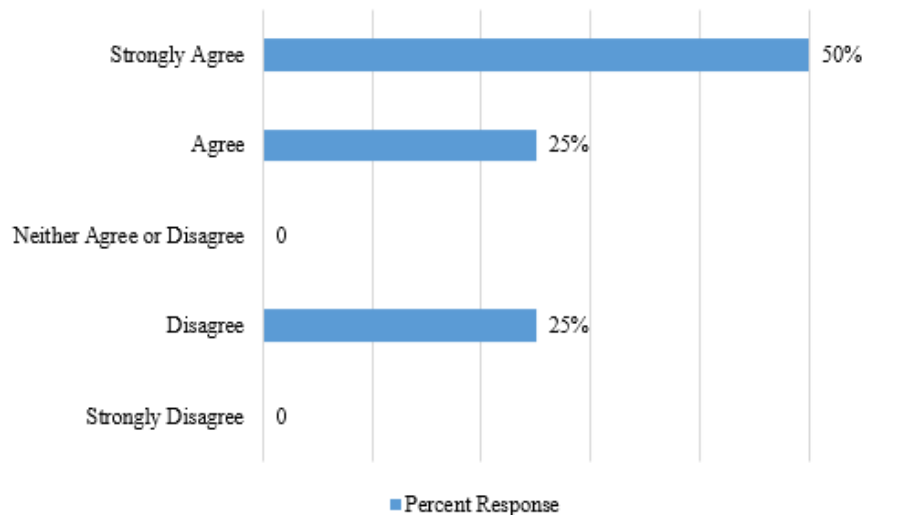


Figure 3. Question 2 – Percentage Responses

Responses to Question 3 – Would you continue giving business to your current provider if things stayed the same?

The percentage response to this question, shown in the figure below, indicates that all the respondents would not continue giving business to the local diagnostics tools' manufacturer should the status quo remained unchanged. This is evidenced through the responses that showed that 25% of the respondents strongly disagreed with the statement and the remaining 75% disagreed with continuing to give business to the company should the status quo remain unchanged.

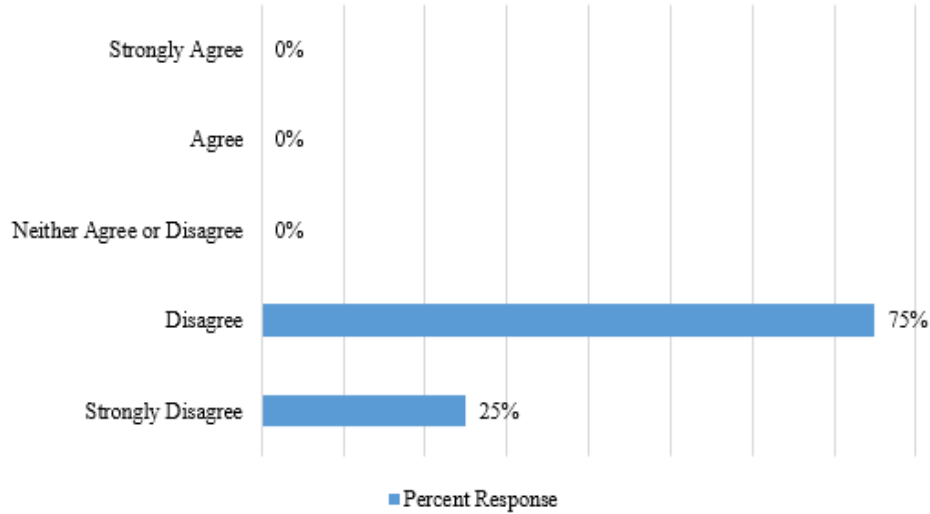


Figure 4. Question 3 – Percentage Responses

4.2. Employees Responses

Responses to Question 4 – Do you know if your customers are currently happy with the services you provide?

As depicted below, majority of respondents agree that their customers are happy with the services they provide. This is evidenced by 47.4% of respondents agreeing that customers are happy with their services and 4% strongly agreeing with that statement.

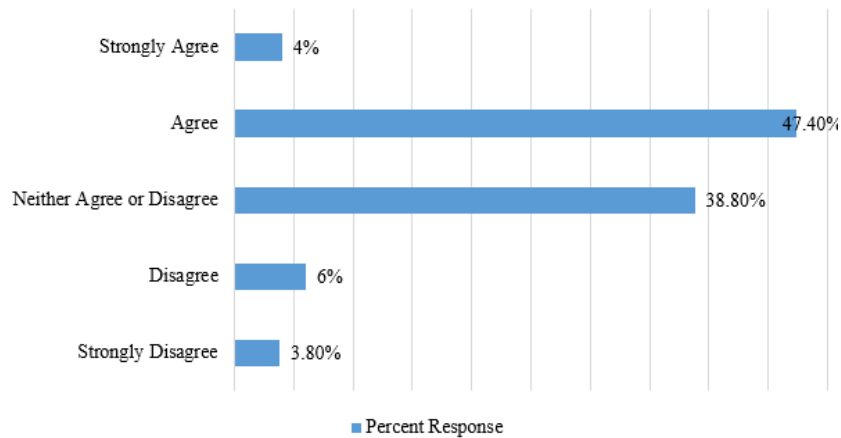


Figure 5. Question 4 – Percentage Responses

Responses to Question 5 – In your own opinion do you think implementation Quality Management Systems (QMS) improves customer satisfaction?

As depicted below, majority of respondents agree that their organisation's implementation of QMS improves customer satisfaction with 26.30% of respondents agreeing, and 58% of respondents strongly agreeing. However, on 11% could not agree or disagree.

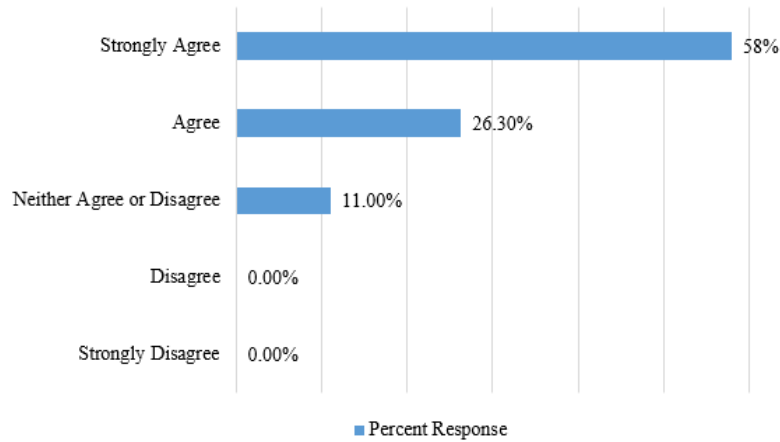
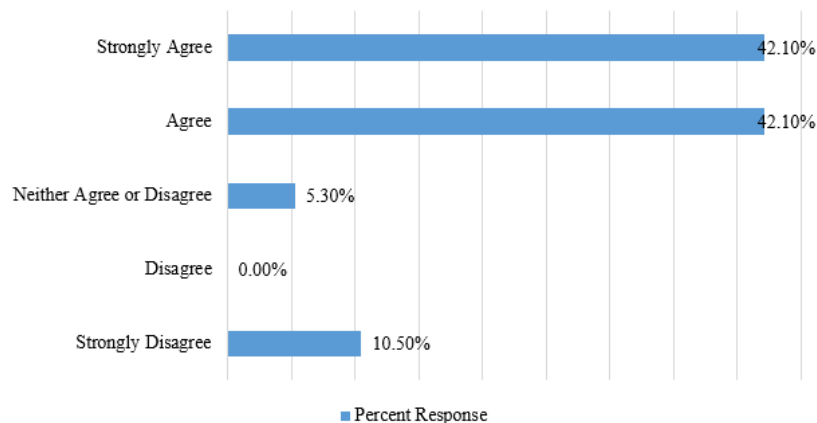


Figure 6. Question 5 – Percentage Responses

Responses to Question 6 – If management chooses to implement a new version of ISO 13485 would you support it?

As depicted below, the survey results show that Management will receive full support from 42% of staff members if they were to implement ISO 13485. Another 42% is very likely to give their support to management. While 5% are undecided about supporting the implementation, 11% of the workers are totally against the implementation of ISO 13485.



5. Conclusion and Recommendations

Based on the statistical analysis of the results, the study shows that the implementation of Quality Management Systems has a positive effect on customer satisfaction, with customers indicating that they would not support businesses, within the medical devices manufacturing sector, that are not ISO 13485 accreditations. Findings also revealed that there is still some reluctance from employees to support the implementation of a new ISO 13485. This is due to the fact that the training provided for the implementation of the current ISO 13485 would interfere with employees' ability to perform their work, and some employees having indicated that it negatively affected their KPI. Clarity was provided on this matter as information regarding the rollout process was not fully available prior to the implementation phase. This conclusion was supported by qualitative data, quantitative data and the number of literature studies for this paper.

It is recommended that the following this study, the local manufacturing company conducts a follow up internal audit, the findings should be compared against the information obtained in the research paper. As a follow up to this study, the researcher aims to conduct another study comparing different companies in the same industry to measure and establish if a full functional QMS has an impact on customer satisfaction.

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