

Customer Satisfaction Survey of Quality Management System in the Medical Industry

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Abstract

The management function of any organization is to ensure that the set goals, visions and objectives of the organization meet customer satisfaction through the implementation of a Quality Management system (QMS). The aim of the study is to reduce the gap between management expectations of set standards and the given performance of the organization by employees, thus finding measures to reduce those gaps and decrease customer dissatisfaction. Primary and secondary questions are aimed to answer the following questions respectively: Will the implementation of QMS through an ISO13485 improve customer satisfaction in a medical diagnostics equipment manufacturing organization? And does staff engagement in the objectives set by management have a relationship to customer satisfaction? The researchers employ the mixed-method approach using a local diagnostics devices manufacturer as a case study. Evaluation of the operations system is done through data collection from employees and customers with the means of questionnaires. The study concluded that through statistical analysis obtained, there was unanimous support of the fact that implementation of a QMS has a positive effect on customer satisfaction, although the acceptance of the system's implementation is not welcomed by minority of employees.

Keywords

ISO13485, Quality Management System, Customer satisfaction

1. Introduction

Looking at a business from a comprehensive vantage point, including all the stages throughout the value chain that is established from the identification of needs within a market, through the conception of a product, until the satisfaction of those needs, it is evident that any organisation that set for itself the aim of satisfying customer needs should consider, in today's complex world where those needs are ever changing, implementing a Quality Management System (QMS) customised to ensure that its process, service or product conforms to the objectives and the purposes for which it is to be used – satisfying the needs of its customers (Murmura and Bravi, 2016). By definition, a QMS incorporate the hierarchical structure, activities, projects and actions intended to guarantee that an item, procedure or administrations adjusts to the goals and the reasons for which it is to be utilized (Murmura and Bravi, 2016). Alternatively, a structured collection of business processes focused mainly on continuously meeting customer requirements and enhancing their satisfaction is known as QMS.

The implementation of QMS has been trusted by many organizations in the past years (Pharm Out, 2016). As unequivocally noted by Murmura and Bravi (2016), in ongoing decades the compliance and use of institutionalized QMS models have been viewed as one of the most basic occasions in quality management advancement and globalization (Ruzevicius, Adomaitiene, and Sirvidaite, 2004; Sheehan and Presenza, 2011; Nabavi, Azizi, and

Faezipour, 2014; Rusko, Sablik, Markova', Lach, and Friedrich, 2014) and organizations have progressively utilized QMS as a device to acquire internal advantages as well as external ones, for example, consumer loyalty and faithfulness (Simon and Honore Petnji Yaya, 2011; Rusko et al., 2014).

A successful business is perceived by the profitability it has or its liquidity. Currently many organizations, within the medical devices manufacturing and related services sector, use ISO13584 standard as guidance to implement quality systems, maintaining improved systems and ensuring continuous improvement in processes with the aim of getting profit and growth (Li, et al., 2015). As Thomas Foster (2010) in his book states that for a business to be successful, there should be a balance between different organizational function areas where a coherent business vision and strategy is met. in order to guarantee that these departments will work together to achieve the set goals and objectives, the people in different operations must be trained and deemed competent in performing their set and well-defined processes. ISO 13485:2016 indicates the prerequisites for a QMS where a company needs to exhibit its capacity to produce medical devices and supporting services that reliably meet client and relevant administrative necessities (International Organization for Standardization, 2016).

The significance of using a QMS in the organization is not only to have well-defined processes in each functional area and requirements for each party being clarified (Butler & Dobert, 2012), but to compare the set standards or performance of the operation which are management expectations with the outcome or results of the operation. These set performance objectives (i.e. quality, speed, dependability, flexibility and cost) should be communicated with the people in the operation. W Edwards Deming's system of basic knowledge and his work today is known as the PDCA (Plan-Do-Act-Check) cycle is widely used as a contribution to the QMS (Gryna, 2001).

1.1. Background, Rationale and Scope of the Study

The Medicines and Related Substances Amendment Act 14 of 2015 defines medical devices broadly to cover everything from disposal syringes to magnetic resonance imaging (MRI) scanners (Saidi and Douglas, 2018). The Act goes further and specify that medical devices include non-invasive, invasive, active implantable, and in vitro diagnostics (IVD) devices, as well as medical equipment, such as suction and oxygen therapy equipment, neo-natal equipment and fluid warming cabinets, and equipment mounting systems (Republic of South Africa, 2016). These definitions are accepted by the South African Medical Device Industry Association (SAMEDI). Worthy of note is that the Act, according to Kirby (2017), established the South African Health Products Regulatory Authority (SAHPRA), which replaces the Medicines Control Council (MCC). As a regulatory authority, SAHPRA is authorized to record IVD medical devices, cosmetics, foodstuffs, complementary medicines, medical devices, or medicines (Geomans, 2017).

In South Africa, the industry of medical device is represented by SAMEDI, which is a non-profit voluntary association, which was established in 1985 and is recognized as an important player in the South African healthcare industry (Samedi.org.za, n.d.). The affiliation, which advances, speaks to and shields the interests of the South African Medical Device and In-Vitro Diagnostics (IVD) industry, centers around medicinal services matters pertinent to its members' advantages and represents the interests of more than 160 organizations that operate in the Medical Device, Medical Equipment and In Vitro Diagnostics sector in South Africa (SAMEDI, 2015).

The industry's value chain is made up of (1) manufacturers (local or international); (2) providers of packaging materials; (3) transport companies that are contracted by medical device manufacturers or users; (4) importers – including local branches of international manufacturers, agents and distributors; (5) customs and excise; (6) regulators such as the Department of Health as well as local and international regulatory bodies; and lastly (7) maintenance and after-sales services providers in-house or outsourced (Who Owns Whom, 2019).

It is estimated by the US International Trade Administration (ITA) that the size of the South African Medical Equipment and Device market, which is quite diverse with more than 600 suppliers ranging from large multinationals subsidiaries, distributors and agents for disposable medical devices to major equipment manufacturers, is \$1.56bn by sales in 2018. The market is expected to grow to \$1.68bn in 2019. Research by Africa Health showed the total market value by revenue in 2018 was R17.3bn, which was lower than the R20bn reported by the ITA. As depicted in Table 1, research by Africa Health showed that consumables accounted for about 15.8%, or R3.31bn to the total market value in 2018. Diagnostic imaging was another major contributor at 13%, or R2.74bn. Patient aids (e.g. patient

monitoring devices and powered mobility aids) contributed around 10%, or R2.1bn, while other medical devices were R6.54bn (Who Owns Whom, 2019).

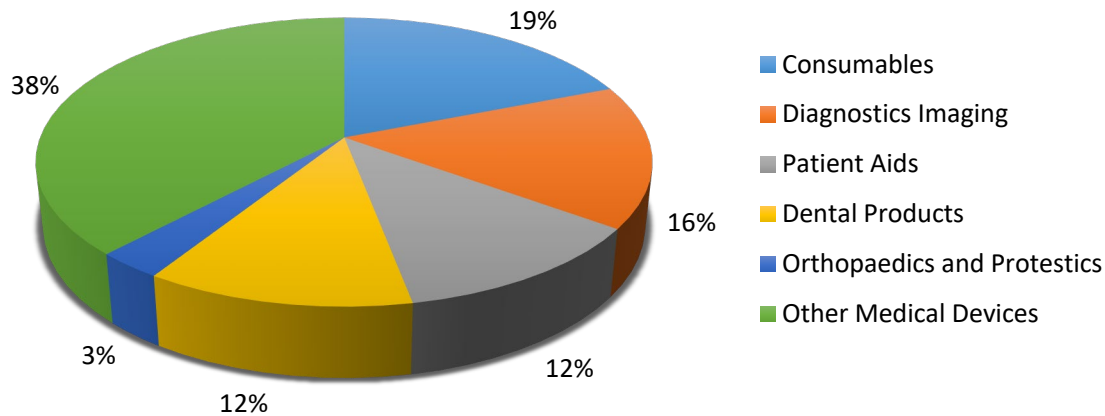


Figure 1. South Africa's Medical Device Market by Product Category in 2018 (Who Owns Whom, 2019)

1.2. Aim, Objectives and Limitations of the Study

The aim of the study is to identify the gaps in the current operations at the local medical diagnostic tool manufacturing company and to establish whether the implementation of QMS will improve the quality and meet customer requirements.

In line with the above aim, the researchers determined the following objectives for this study:

- To identify gaps in the current system so as to establish a baseline for the starting point should the implementation of QMS be an option.
- The information obtained from customers and employees to document a plan of action improving customer satisfaction and improving operations.
- To implement the planned recommendations and work towards implementing an ISO certification.

Although this study contributes to body of knowledge with regards to the implementation of QMS in improving organizational process and customer satisfaction from the perspective of diagnostics tools manufacturing in South Africa, the main limitation is the fact that this study only describes the impact ISO implementation has in one company. Therefore, the findings from this study cannot be generalized and applied to the whole industry. Another limitation of this particular study is associated with time constraint in conducting this research resulting in limited data being collected.

2. Brief Literature Review

The management improvement practices were created by the ISO, such as ISO 14001, specifically connect the existing international standards well-known as Quality Management Standard (Delmas and Montes-Sancho, 2010). The implementation framework of ISO includes three parts performance namely: the first aims at building the foundation to quality systems, secondly to improve the system and lastly focuses on the training, leadership and the enforcing the quality culture. (Ingason, 2015). Delmas and Montes-Sancho (2010) in their research advocated three stages management practices for institutionalizing ISO in the organization. Pre-institutionalization which comprises of few fewer individuals who adopt with limited knowledge, semi-institutionalization involves impartially spread but not permanently engraved in the organization, and lastly full institutionalization which compromises of the making ISO as part of the daily operation of the organization.

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.

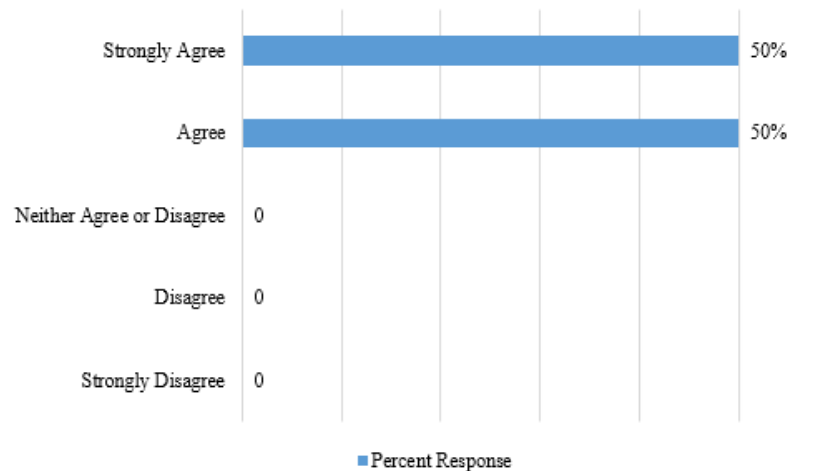


Figure 2. Question 1 – Percentage Responses

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.

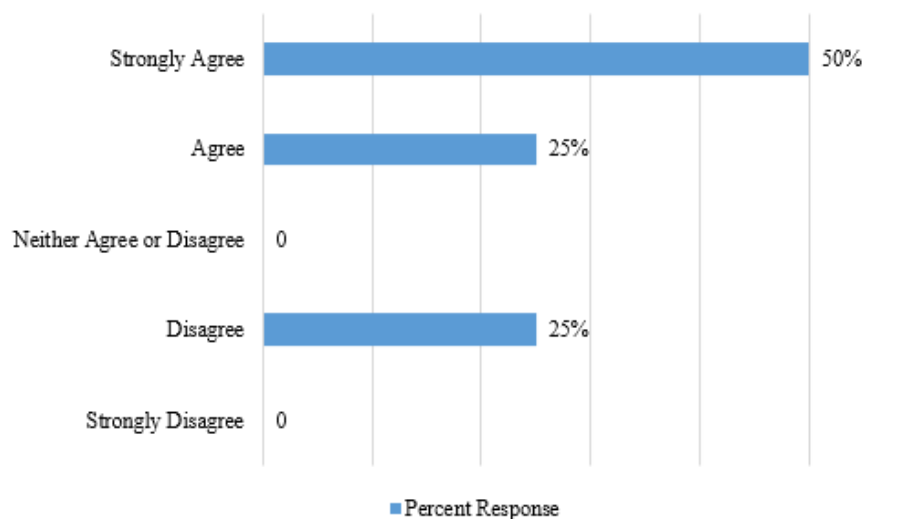


Figure 3. Question 2 – Percentage Responses

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.

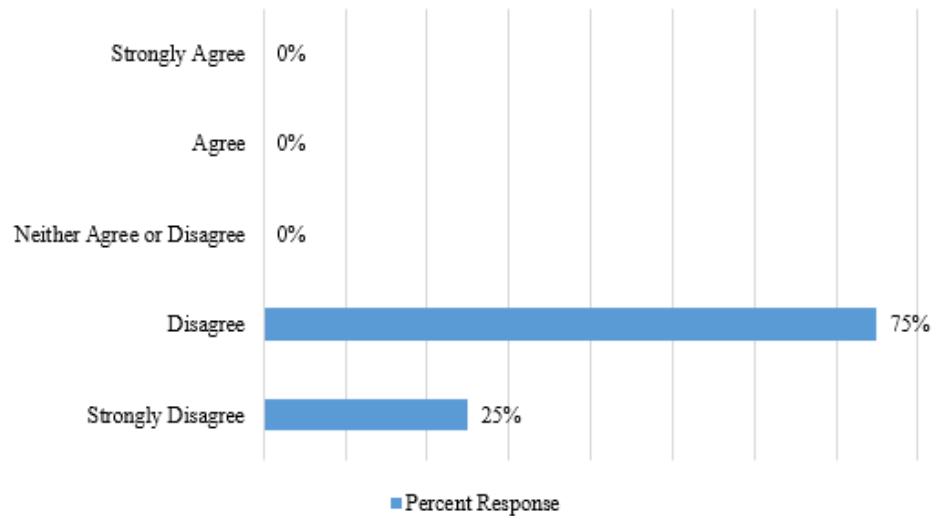


Figure 4. Question 3 – Percentage Responses

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.

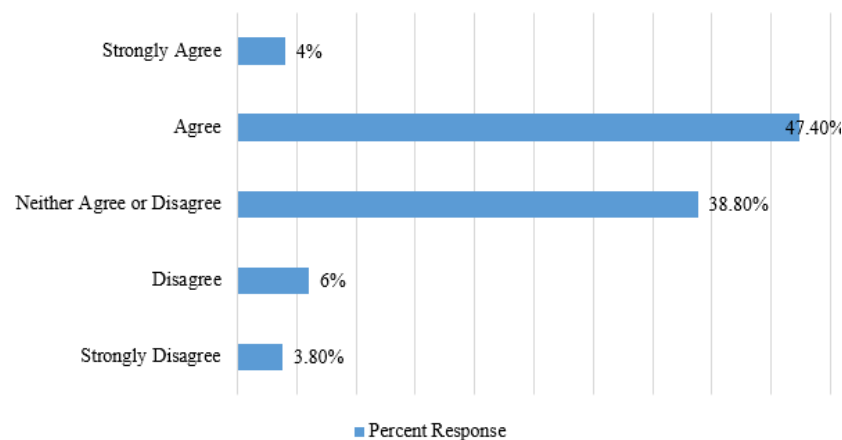


Figure 5. Question 4 – Percentage Responses

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.

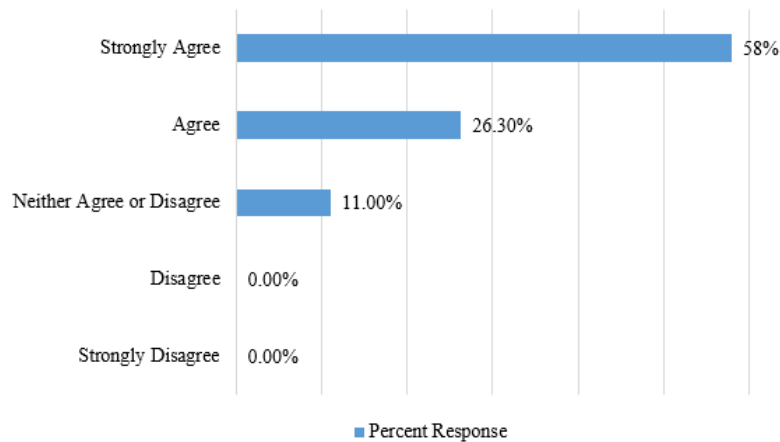
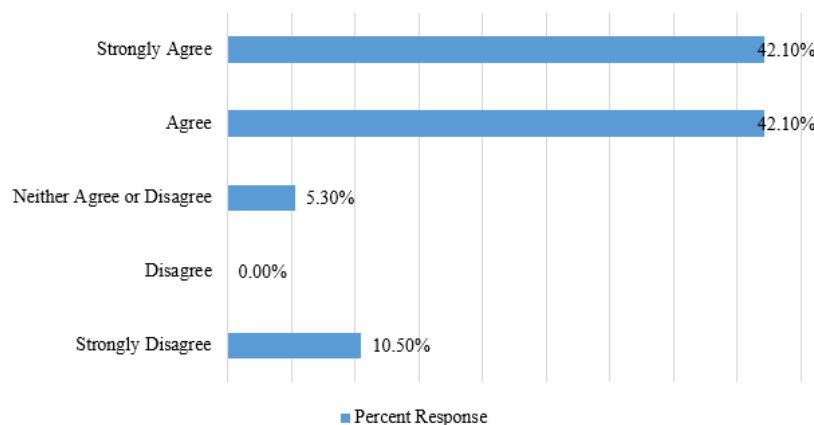


Figure 6. Question 5 – Percentage Responses

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.

Acknowledgements

We like to demonstrate our appreciation to Professor Charles Mbohwa, Executive Dean from the Faculty of Engineering and the Built Environment at the University of Johannesburg, for his immense guidance in the field of as well as for funding this project through his research grant. We would also like to thank the Department of Quality and Operations Management at the Faculty of Engineering and the Built Environment of the University of Johannesburg for providing the facilities that allowed this research to be completed.

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Temosho Bapela has completed Baccalaureus Technologiae graduate in Management Services at the University of Johannesburg. Now an alumnus still interested in research, he is currently working in the engineering environment in order to acquire experience to pursue a masters of technology in the engineering management field.

Sambil C. Mukwakungu is an award-winning academic who has been lecturing Operations Management to first year students, Food Production, and Quality Management at the University of Johannesburg since 2009. His passion for teaching and learning has allowed him to make a difference in at least one student's life every year. He is a researcher who is still establishing himself in knowledge creation with keen interest in Service Operations Management, Lean Operations, Continuous Improvement, as well as business innovation and innovation in Higher Education. He was awarded Best Track Paper Awards at the 2016 IEOM Conference in Rabat, Morocco, also at the 2018 2nd European Conference in Paris, France, and he is together with his team from the IEOM UJ Student Chapter a recipient of the 2018 IEOM Outstanding Student Chapter Gold Award for exceptional chapter activities and contributions to the field of industrial engineering and operations management.