

Implementing a Quality Management System to Improve Customer Satisfaction: A Study of a Medical Devices company

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Abstract

Customer satisfaction plays a very significant role in the success of any business. Increased customer satisfaction ensures business continuity. Implementing a Quality Management System (QMS) is one of the ways to improve processes in an organization therefore improving operations and improving the quality of service. Certification through QMS administers the measurement of performance for processes and ensures continuity of the improvements. ISO 13485 is a standard which represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. The standard is in harmony with the ISO 9001, with additional requirements to guide the medical device industry. A questionnaire was administered to the top five customers and employees of small medical devices company. When questionnaires were analysed, the response received had supported the researcher's idea, that the implementation of a QMS has a positive effect on customer satisfaction. Through the findings of the study, several gaps were identified from the current operations, and through these gaps, improvement can be implemented utilising QMS principles that have been proven to play a major role in continuous improvement and customer satisfaction over the years as indicated in the literature review of the study.

Keywords

Quality Management Systems, Medical Device Industry, ISO 13485, Customer Satisfaction

1. Introduction

1.1 Introduction and Background

In basic terms a quality management system is defined as a structured collection of business processes with a purpose and aim of ensuring that industries meets and exceed the needs of the customer base that they are targeting for their business. Implementing quality management system as the tool to improve company operations thus improving customer satisfaction has been used by different organization over the years (Pharm Out, 2016). Thomas Foster further states in his book that to be successful; a business must balance the needs of different functional areas around a coherent business vision and strategy (Foster, 2010). In this case then a successful business is defined as a business that is profitable, a profitable business is a business that retains its customers by increasing customer satisfaction and growing the business.

Quality management is essential for organisations that want to improve the state of current operation in their organisations. Implementation of quality management can be achieved using various tools and principles. What is important in the implementation process is ensuring that interrelated processes are defined in each function and requirements for each party are clarified (Butler and Dobert, 2012). Quality management system is not just a series of variables and relationships but rather an interconnected interdisciplinary network of people, technology, procedures, facilities and legal requirements etc. to achieve an end. This means that in order to guarantee that the different departments in an organisation are working together to ensure that the vision and mission of the organisation is achieved, there has to be defined processes on the different operations of the organisation, personnel

must be trained and deemed competent in performing their duties and in addition to this management expectations on the performance of company should be communicated to people in all levels in the organisation (Foster, 2010). Different scholars in the field of quality management have written different principles that assist organisation in implementing quality management system. One of these great scholars is W Edwards Deming who is known for the Deming's chain reaction, the Deming's system of basic knowledge and his work on what is known today as the PDCA (Plan-Do-Act-Check) cycle that is widely used in the implementation of quality management system. (Gryna, 2001)

Currently, many organisations are using ISO standards as guidance to the implementation of a quality system, maintaining the improved system and ensuring continuous improvement in processes with an aim of ensuring profitability and growth of the organisation. (Li, et al., 2015). ISO organisation is an international standard setting body composed of representatives from various national standard organisations. ISO standards are used internationally. This is useful as most organisations trade globally and it is important to ensure that the quality of work is maintained throughout these global operations. Most organisations are multinationals and in order to ensure that the level of manufacturing, production and service is maintained across board implementation of a known worldwide ISO standard is the preferred way that will guide personnel, measure performance by providing regular audits and management reviews to ensure performance in the different nations is kept within the required specifications.

1.2 Problem statement

This paper will investigate the challenges faced by a medical device company including to the risk of losing its key customers if the current situation does not change. From the literature reviewed research shows that dissatisfied customers have the power of sharing their dissatisfaction with other potential customers in the industry resulting in loss of revenue for the company.

1.3 Aim

The researcher also aims to obtain information from customers and personnel on areas that may be pain points and areas where improvements may be necessary. The researcher aims to establish the need to implement a QMS for this organisation

1.4 Objectives

The objectives of this paper are as follows:

- a) Using the information obtained from feedback from customers and employees to document a plan of action improving customer satisfaction and improving operations
- b) To establish whether certification through ISO 13485 would be a viable option for this medical device company
- c) To identify gaps in the current system so as to establish a baseline for the starting point should the implementation of a QMS be an option.

1.5 Primary research question

Will the implementation of a quality management system (QMS) through an ISO 13485 improve customer satisfaction in a diagnostics organisation?

1.6 Secondary research question

Does staff engagement in the objectives set by management have a relation to customer satisfaction?

2. Literature Review

QMS and Total Quality Management (TQM) is used interchangeably by various authors. (Sadikoglu and Olcay, 2014) defines TQM as the firm-wide management philosophy of continuously improving the quality of services, products and processes by focusing on the needs and expectations to enhance customer satisfaction and firm performance. According to (Butler and Dobert, 2012), QMS is defined as a means of improving operations by implementing controlled written processes she further adds that an effective quality management system identifies key processes and steps and prevents most failures before they occur. TQM is defined as the strategy that is aimed to establish high quality of products and services that cover all customer demands and achieve the highest levels. (Al-Qahtani N D, Alshehri S. and Aziz S.S, 2015). QMS is all procedures explicitly designed to monitor assess and

improve quality. (Wagner, et al., 2006). Quality management is a direct result of the understanding that the main factor in maintaining and increasing the number of customers but improving the quality of products supplied and services rendered to them. (Stanciu A, Constandache M and Conderia E., 2014). It is clear from all these definitions of QMS or TQM systems that the focus on improving operation in various industries is to enhance customer satisfaction, therefore improvement in the quality of operations in an organisation is directly related to improved customer satisfaction thus resulting to profitability.

Different techniques of identifying gaps were used by various authors, identifying gap /starting points also assists companies to measure improvement following the implementation. This information can be shared with partners and shareholders. For (Wagner, C, Gulacsi L, and Outinen, M, 2006) the method of gathering information for this study was the use of questionnaires that were distributed to hospitals in these 3 counties. The conditions for completing the forms were that snr management of the hospitals should complete the questioners. In collecting the data it was noted that response on submitting the completed questioners was better in the country that had formal quality policy legislation that the other countries where telephonic follow up had to be implemented in order to receive feedbacks . Another method used by one other author was based on customer satisfaction where the ground work was performed by measuring customer satisfaction. The satisfaction index is the analytic hierarchy process that was used. The authors hope that the results obtained from this will be useful to anyone who wants to implement a QMS in their organisation (Nabavi, et al., 2014). Measuring performance in terms of quality experienced different approaches: compliance with specifications, customer satisfaction, and generally of all stakeholders of the organization. Thus, performance evaluation may be introduced at all levels of an organization (Stanciu, et al., 2014).

There were various methods and tools used by various authors for implementing quality management systems on the literature reviewed for this paper. Tools such as statistical analysis and control plans, failure modes, affects analysis, system validation protocols and Good Manufacturing Practices (GMP) where the authors emphasises on the fact that a good QMS should be auditable and further states that auditing is a tool to measure that operations are carried out in accordance to documented procedures that are approved by the organisation's QMS (Butler and Dobert, 2012). (Nabavi, et al., 2014) this paper referred ISO 9001 :2018, (Al-Qahtani, et al., 2015) referred to the Implementing quality control, quality assurance and continual improvement and (Stanciu , et al., 2014) relates to the ISO 9004, 2009. Lachapelle and Hundozi, 2013 state that ISO 13485 is a standalone Medical device Quality management Standard that is appropriate for all sizes and industries involved in the lifecycle of a medical device pursuing improvements on its operations. This paper further states that this ISO standard is built on ISO 9001. The benefits of this standard in medical diagnostics industries include; establishing, documenting, a QMS and maintaining its effectiveness, ensuring conformance with the organisations stated quality policy, demonstrating conformance to interested parties such as Customer and Collaborators, the organisation making a self-declaration of conformity with the quality standard, it has become a common practice for organisations who are trading international to demonstrate conformance to a quality standard. (Nabavi, et al., 2014) in analyzing customer satisfaction weighs the effective criteria through analytic hierarchy process by identifying 5 focal groups for the reseach i.e. price and sales terms, aftersales terms, product delivery terms, quality of the applied raw materials and technical specifications of the product and after analysis of data it was noted that the price and sales terms of products have a significant impact on customer satisfaction. The study is concluded by stating that ISO9001 quality management system has been able to improve customer satisfaction within the 11 month period that the study was in progress.

Once an organisation has acquired certification in the ISO 13485 as stated by (Lachapelle and Hundozi, 2013) there is ; better understanding of the organisation, confidence of clients, contract compliance, legal compliance, competitive advantage, reduction of costs

Implementing a quality management system and regulatory compliance can be costly in the end the benefits outweighs the cost.

(SIrois, 2015) in his article regarding the advantages of ISO certification states that implementing a QMS requires compliance to the standard by ensuring the implementation documenting of policies for records control , internal auditing, procedures, non-conformances, process design traceability and accountability. He further indicates that in addition to gaining new markets compliance reduces operational costs by improving efficiency, consistent delivery of high quality product and services, systemically addressing customer complaints increases customer satisfaction And finally that complaints, surveillances and product recalls are handled in a transparent manner proves commitment to quality

(Miller, 2007) Indicates in his paper that with the growth of outsourcing there is an emphasis on quality management uniformity between manufacture and supplier, in countries such as Europe the regulatory TUV Rheinland

encourages manufacturer to source from suppliers that are ISO 13485 certified. Mitigating the risks in organisation that outsource activities or obtaining supplies organisation needs to ensure QMS parity. Parity is ensuring that the critical vendors also possess the ISO 13485 certification as the main organisation that they are supplying to.

It is evident from the literature reviewed that by implementing a relevant accreditation method as a quality management system for any organisation is vital. Implementation of an ISO accredited method can be very costly but in the long-run the results of a fully functional QMS will ensure that the organisation satisfies its customers and that profitability of the organisation improves, it also ensures that the apparent risks are mitigated

3. Methodology

3.1 Research design

The aim of this paper is to answer the research question: Will the implementation of a of a quality management system (QMS) like an ISO 13485 improve customer satisfaction in an organisation?

In strategizing for this paper the researcher aims to employ the mixed method approach. Qualitative, quantitative from questionnaires and Case study approach will form the mix method in this context. Mixed methods research makes use of multiple ways to explore a research problem including using methods where research problems becomes research questions and/or hypotheses built on prior literature, understanding, experience of the research process (<https://researchrundowns.com>). Jeff Sauro further explains the categories of qualitative research methods into 5 categories or groups such as: ethnography, narrative, phenomenological, grounded theory, and case study (Jeff Sauro, 2015). Researcher Robert K Yin defines a case study method as an empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident and in which multiple sources of evidence are used (Robert K Yin, n.d. 1984).

3.1.1 Measures

The researcher will use content analysis of document to identify key themes in the research. Content analysis a wide and heterogeneous set of manual or computer-assisted techniques for contextualized interpretations of documents produced by communication processes or implication of processes having an ultimate goal the production of valid and trustworthy inferences (Wikipedia, the free encyclopaedia).

3.1.2 Credibility

In order to obtain truthful information the employees the questioners will be completed anonymously using an online questionnaire. Employees will be given a limited time to complete the questionnaire. The customers will be given an option to reveal themselves or to remain anonymous and the customer feedback will be conducted online.

3.1.3 Transferability:

Transferability in qualitative research is defined as as the degree to which the outcomes of a research can be applied or transferred beyond the bounds of the project. Transferability implies that results of the research study can be applicable to similar situations or individuals. (<http://universalteacher.com>). From the literature reviewed in this paper it is evident the best approach used in similar situations self-administered questionnaires as it the quickest options when dealing with professionals as time is very precious in these environments.

3.1.4 Dependability

Dependability on the data obtained in this study can be easily assessed online as the questionnaire created via google drive will be forwarded to the selected population via a link without any interference by the researcher. The feedback and summary can the reviewed via the audit trail of the of the google drive used to provide the questionnaires.

3.1.5 Confirmability

The analysis of the employee and customer feedback will be conducted online. This will ensure that the information from the respondents is obtained as is with absence of biases from the researcher

3.1.6 Limitations, Assumptions and Significance:

Some members of staff might not cooperate and complete the questionnaires honestly; therefore the sample might not reflect the true population. Some employees may choose not to participate on research for the same reason. Time may also be a limiting factor in this study as there is only 6(six) months to complete the research.

The researcher hopes that by asking the question in this paper will reveal the need for the company in question to implement a quality management system to improve customer satisfaction. It would then be important in this case to get buy-in from the senior management to encourage the employees to participate in the research as the aim is to improve the current system and improve customer satisfaction

3.2 Population and Sampling

Sampling for this paper will include all 25 employees from the organisation and Customer feedback forms that will be distributed to the top 5(Five) customers of the organisation. The researcher targeted the top five customers as the intention is to retain these customers therefore retain revenue.

3.3 Data Collection

Data collection will be conducted using anonymous questionnaires for both primary and secondary data, these will be circulated across different levels of employees in the organization and customer feedback forms to the top 5 customers in the organization. For the top 5 customers the reseacher will focus the questionnaires on post delivery services in order to evaluate the level of service the customers receive. The employee questionnaires will be orientated around the present state to assess the need for improvement. A combination of open ended and close ended questions will be used for the questionnaires. Consistency matrix is a tool chosen to assist in the design of the the questionnaires . The consistency matrix linked the objectives of this paper , literature reviewed and gave direction for Analysis.

Table 1. Consistency matrix

Investigate (Sub Research questions	Literature Resources	Measurement Question	Analysis
Is the implementation of a QMS essential to ensure customer satisfaction in an organization?	(Sidikoglu and Olcay, 2014), (Butler and Dohert , 2012), (Al-Qahtani, et al., 2015), (Wagner, et al., 2006) (Stanciu, et al., 2014), (Lachapelle and Hundozi, 2013) (Miller, 2007)	<u>Customer questionnaire</u> Question 3 and 4 <u>Employee questionnaire</u> Question 1 and 2	Content Analysis
Will identifying gaps in the current system assist in guiding the implementation of a QMS?	(Wagner, et al., 2006), (Nabavi, et al., 2014), (Stanciu, et al., 2014)	<u>Customer questionnaire</u> Question 2,3 and 5 <u>Employee questionnaire</u> Question 4 and 6	Content Analysis
What other methods of quality management available for organisations to use?	(Butler and Dohert , 2012) ;(Nabavi, et al., 2014), (Al-Qahtani, et al., 2015), (Stanciu, et al., 2014)	<u>Customer questionnaire</u> Question 1 <u>Employee questionnaire</u> Question 5	Content Analysis

3.4 Data analysis and interpretation

Data will be analysed using statistical methods. Pie charts and bar graphs will be utilized for the intepretation of this data.

3.5 Reliability

In this paper the researcher aims to use Cronbach alpha to measure the reliability as it is the most commonly used method when you have multiple questionnaires that forms a scale and the resecher aims to determine if the scale is reliable. Cronbach alpha is a measure of internal consistency relating to how closely related a set of items are as a group. It is considered to be a measure of scale reliability. (Anon., n.d.) Results for Cronbach alpha a rate are analysed as follows:

0.95 indicates exceptional correlation

0.80 indicates good reliability

0.70 indicates acceptable correlation

4. Analysis of data

4.1 Quantitative data analysis

4.1.1 Top 5 Customer responses

Out of the 5 top customers who were forwarded the customer feedback form only 4 responded, therefore 80% response rate was obtained. For this paper data will be schematically represented by pie charts and bar graphs followed by a summary iteration by the researcher.

1. Do you think ISO accredited companies provide better service than companies that are not ISO accredited?

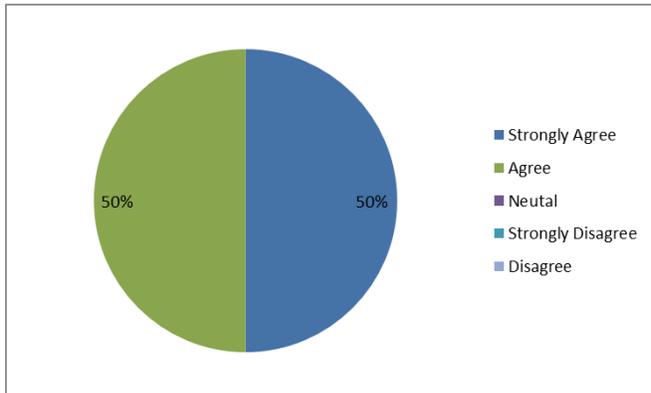


Figure 1. Services provided by ISO accredited companies.

Data shows that 100% of customers felt that ISO accredited companies provided better service than companies that are not ISO accredited. 50% strongly agreed while the other 50% agreed.

2. Do you think the current service given to you can improve?

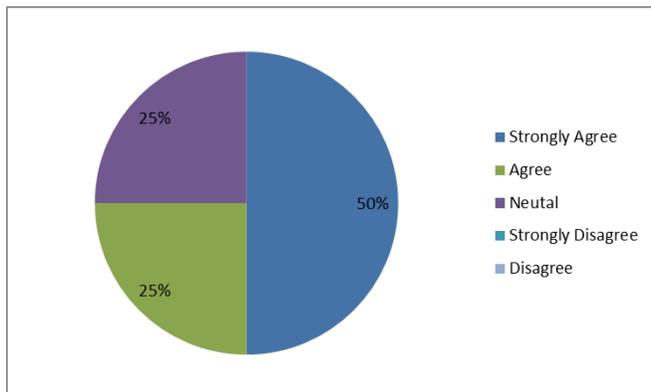


Figure 2. Service improvement.

Data indicates that 50% are strongly in agreement with the statement that the current service can be improved while 25% agreed that service can be improved but not as strongly as the other 50% and the other 25% were neutral therefore indecisive.

3. Would you continue giving business to your current provider if things remain the same?

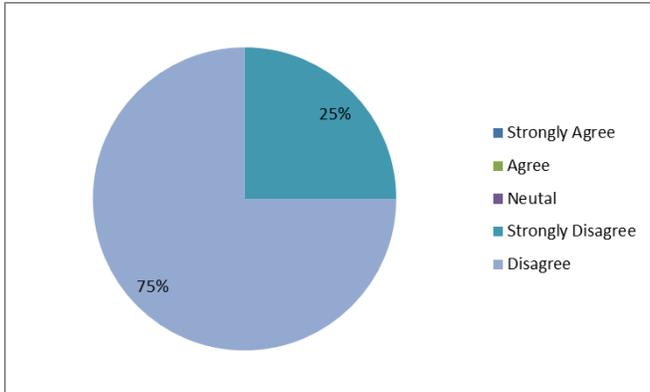


Figure 3. Improvement to current service.

Data analyzed reveals that 75 % of the customers were willing to change providers if the current service remained the same and only 25% of customers would remain loyal to the company even in these current conditions.

4. Please rate from a scale of 1-10 level of service provided by your current supplier.

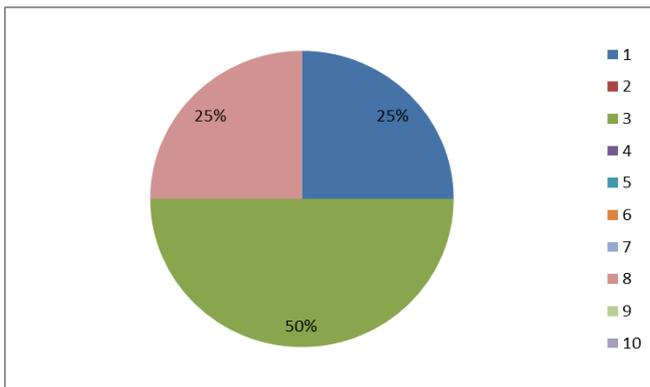


Figure 4. Rating level of service.

When the customers were asked to rate the level of service on a scale of 1-10 with 10 being the highest rate, 50 percent rated the level of service as a 3, 25% rated them as a 4 while the other 25% rated them as a 6

4.1.2 Employee Feedback

Out of the 25 employee feedback forms that were forwarded to the employees in the company only 19 employees responded therefore 76% response was received. Again data will be schematically represented by pie charts and bar graphs followed by a summary interpretation by the researcher.

1. In your own opinion do you think implementing quality management Systems (QMS) improves customer satisfaction?

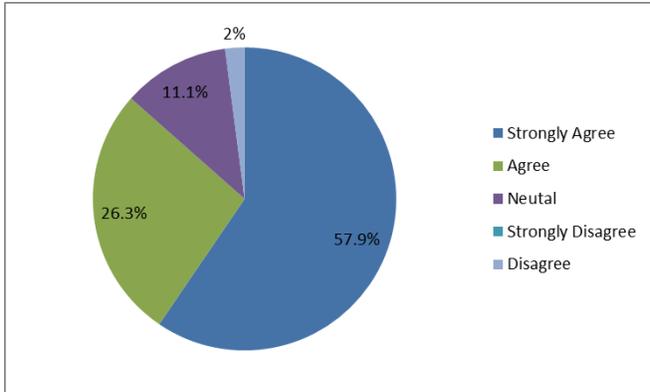


Figure 5. Implementation of QMS in relation to Customer services.

84.2% employees selected a combination of Agreed and Strongly Disagreed in support of implementation of QMS improving customer satisfaction, 11.1% were neutral and 2% disagreed with the statement.

2. Do you think that implementing QMS will add more administrative tasks to your role?

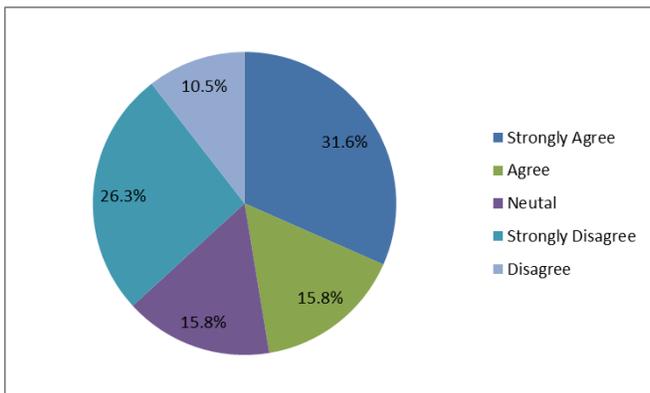


Figure 6. Additional administrative tasks.

For this question data revealed that 31.6% Strongly Agreed, 15.8% Agreed, 15.8% were neutral 10.5% Disagreed while 26.3% strongly disagreed with the notion that implementing a QMS will add more administration to the role.

3. Are you happy with your job?

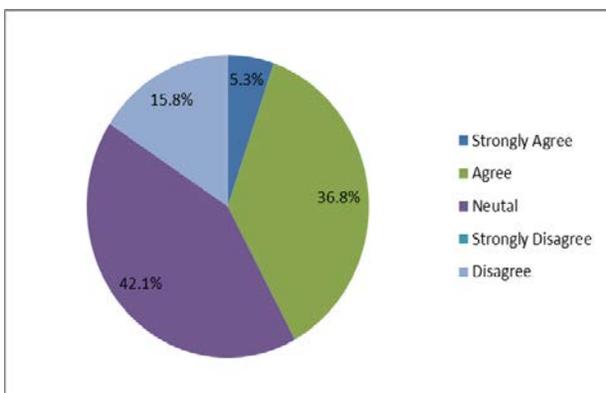


Figure 7. Job satisfaction .

Data indicating job satisfaction of employees in the organisation revealed that 42.1% were not sure how they feel, 36.6% were happy, 15.8% were not happy at work and 5.5% were contented in their jobs.

4. Do you know if customers are currently happy with the service you provide?

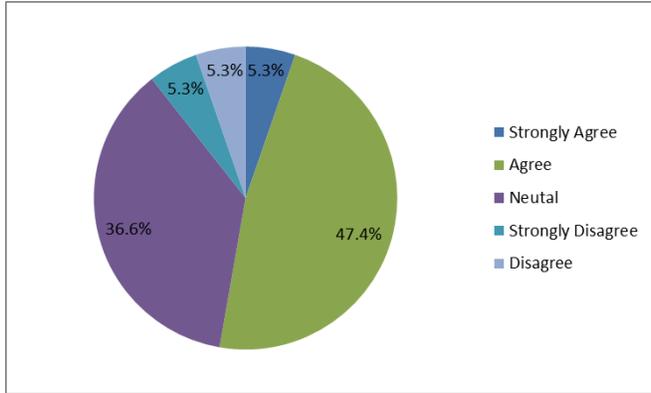


Figure 8. Customer satisfaction .

When employees were asked if they thought that customers were happy with the current service 47.4% indicated that customers were happy, with 36.8% were neutral followed by 5.3% who were very happy and 10.8% unhappy.

5. If management chooses to implement ISO 13485 would you support this decision?

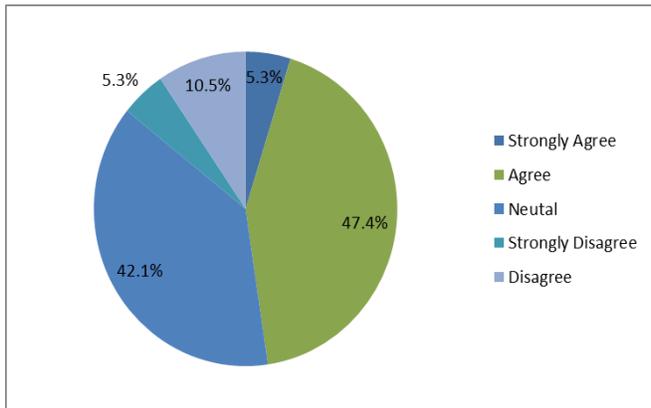


Figure 9. Support towards implementation of ISO 13485.

When employees were questioned if they would support the implementation of an ISO certification 42.1% would definitely support management, 47.4% would most likely support management, 10.5% would not support management and 5.3% disagree while the other 5.3% were undecided. For question 5 from the response received it looks like most employees were in support of the implementation of a ISO 13485 that is specific to their industry of medical diagnostics.

6. Would you refer you family or friends to work at your current employer ?

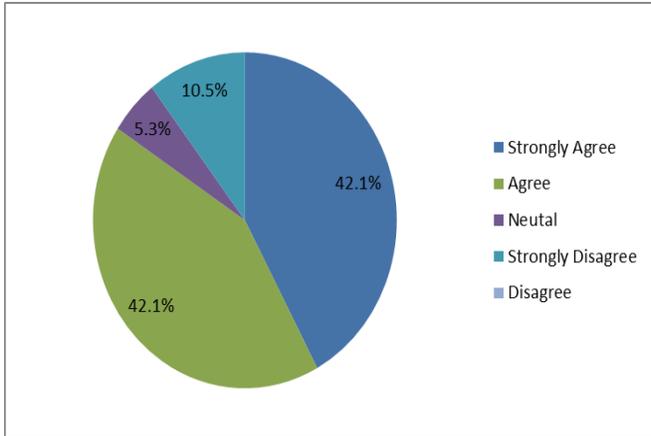


Figure10. Employees rates job satisfaction.

When employees were asked if they would refer people to work at the current employer 31.6% were happy to refer people they knew for job opportunities, 31.6% were unsure, 21.1% would rather not refer people, 10.5% would definitely not refer anyone

Question 3 and question 6 were similar in style and controversial in nature. The researcher added these questions to establish more or less if the employees were satisfied with the conditions of their work space. The rationale behind these questions was to confirm job satisfaction, as dissatisfied people will rarely refer loved ones to places they loathe. From the responses received it seemed that people were positive mostly and negativity was linked to salaries, challenges with working with people based on the response given by employees when requested to justify their responses.

4.2 Qualitative data analysis

When qualitative data obtained from the justification text of the questionnaire was analysed both customer and employees yielded majority positive responses. In the graph below Yes=Positive and No=Negative.

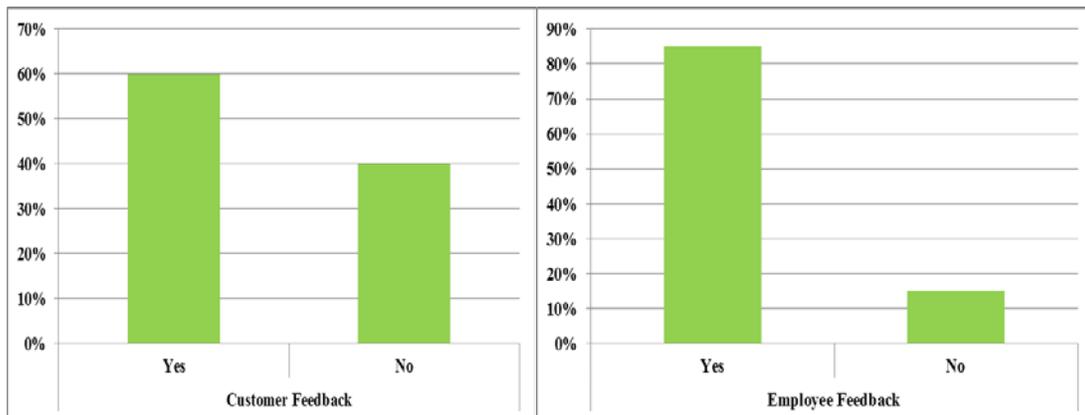


Figure 11. Justification of questionnaire response.

5. INTERPRETATION OF DATA

5.1 Statistical analysis of data

Each question in the customer and employee feedback questionnaire was analysed using statistical techniques and the results for Cronbach alpha as stipulated below;

Table 2. Customer feedback results

Cronbach alpha	0.70
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Table 3. Employee feedback results

Cronbach alpha	0.80
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Cronbach alpha Coefficient was used for the measure the reliability of the data and the results obtained were 0.7 for customer feedback and 0.80 for employee feedback. Results from data analysis for the questionnaires indicates that data obtained was of acceptable correlation and reliable.

6. Conclusion

Based on the statistical analysis of the data for this study the results obtained from the customers support the idea that implementation of a QMS has a positive effect on Customer satisfaction. This statement is supported by both the qualitative and quantitative data obtained from the results of the questionnaires. This is in agreement with the conclusions made from the number of literature for this paper. Cronbach alpha also shows that analysis of data from this paper shows good correlation indicating that the data is reliable. Also from the information obtained from the questionnaires several gaps were identified from the current operations at this company, and through these gaps improvement can be implemented through the use of a QMS principles that have been proven over the years. A follow up internal audit should be conducted for the company and the findings should be used to verify the information obtained from this research is correct. As a follow up to this study the researcher intends to conduct a follow up study comparing different companies in the same industry to measure and establish if a fully functional QMS has an impact on customer satisfaction.

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Biographies

Nita Sukdeo is currently a full time senior lecturer in the field of Quality and Operations Management, and the BTech Quality programme leader in the Department of Quality and Operations Management, at the University of Johannesburg, Gauteng, South Africa. She obtained a Masters in Quality from the Durban University of Technology and a PhD in Engineering Management from the University of Johannesburg. She is an upcoming young researcher in the field of total quality management and operations management. Her field of expertise also includes quantitative analysis, quality management systems, and quality auditing and risk assessment. She is a qualified Lead Auditor, proficient in ISO standards and certification. She is one of the directors of the Society for Operations Management in Africa (SOMA), as well as a senior member of the South African Society for Quality (SASQ).

Nombulelo Gqamane is a quality practitioner in the Intra venous (IVD) medical devices industry. She has over 20 years' experience working in the IVD medical devices field specializing in quality management, clinical trials and training of personnel. Nombulelo holds a National diploma in Biomedical Technology (Clinical Pathology) from the Cape Peninsula University of Technology, a certificate in project management, B Tech Quality from the University of Johannesburg and currently studying towards Masters in Operations Management. In her current role she has led the implementing QMS through ISO 13485: 2016 and implementation of relevant regulatory requirements. A certified ISO 13485 auditor with a natural affinity and passion for problem solving, impressive organizational skills and a thirst for knowledge. Previous expertise includes setting up laboratories in Southern and Eastern Africa and ensuring compliance to Good Clinical Laboratory Practices (GCLP).