ASSESSING EMPLOYEE PERCEPTIONS OF QUALITY AT FRESENIUS KABI MANUFACTURING SOUTH AFRICA (FKMSA)

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ABSTRACT

The pharmaceutical industry is one of the fastest growing and developing industries in the world today. With the ever advancing technology and manufacturing techniques, quality assurance has become the focus of regulatory bodies all over the world. The implementation of quality management systems (QMS) that ensures that quality is built into every step of the design and manufacturing process has been the focus of many pharmaceutical companies.

With the implementation of quality systems, employee's perception of those systems and overall quality standards of the organisation is very important in establishing the quality culture of the organisation. To benefit from sustainable quality systems the organisations must ensure that employees understand the importance of the systems and that employee's take personal responsibility for ensuring that their functions are performed correctly the first time.

FKMSA has invested in a QMS that seeks to integrate all quality issues. The quality system includes documentation, deviations, corrective and preventative action (CAPA), change controls and quality risk management (QRM) in the entire facility. This system is administered by the quality control department, but each department takes ownership for their quality issues with support and guidance from the quality unit.

FKMSA also firmly believes that quality cannot merely rely on the quality control test results; every step of the production process has a quality aspect built in to ensure that quality standards are adhered to. Every employee is trained, assessed and deemed competent before they can perform their duties; this is to ensure that human errors are kept to a minimum.

Employee's perception of quality is an integral part of quality assurance and it is important for the organisation to know what the employees believe to be the company's standards of quality.

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CHAPTER 1- INTRODUCTION

1.1 INTRODUCTION

The South African pharmaceutical industry is experiencing major changes and challenges. These challenges include the increase of generic medicine manufacturing and utilisation and the burden placed on the health care system by the growing number of people taking anti-retroviral drugs. The proposed National Health Insurance (NHI) scheme is also expected to have major repercussions on the pharmaceutical industry. However, research conducted by Industry Research Solutions shows that the South African pharmaceutical industry will grow at an approximate annual rate of 22% during 2010-2013 (Omnisurge, 2012).

The pharmaceutical industry is an important sector of the health care system in South Africa and is regulated by The Medicine and Related Substance Control Act 101 of 1965. Thus any fault in product design or manufacture can have serious or fatal consequences. Hence inadequate quality of drugs is not only a health risk but also has a severe financial impact on both the manufacturer and individual consumers.

The maintenance of the quality of the product during every step of production with continuous improvement is very important for pharmaceutical industries. Therefore concepts such as Total Quality Management, Quality Management System and International Standard for Organisations (ISO) 9001:2008 were established to ensure that quality is built into the entire manufacturing process and that everyone in the organisation will play an integral part in maintaining quality (Ahamed, 2011).

This is a critical and competitive business environment; hence sustainable competitive advantage and sustainable profitable growth become serious business features. Several core competencies and success factors become important and most important amongst these factors are product quality. A suitable, internal quality improvement principle, among employees, will ensure a more competitive and successful organisation, as well as the internal development of the employees, in order to improve and sustain customer service.

Employee perceptions of quality at Fresenius Kabi Manufacturing South Africa (FKMSA) has not been determined as a tool to assess employee commitment and their quality principles in line with the current Quality Management system which is based on ISO 9001: 2008 and good manufacturing practice. Quality improvement initiatives are mainly driven by the quality departments with both proactive and reactive participation by other employees.

The main goal and objective of FKMSA is to provide a quality product to patients and it is hence vital to establish the employee's perception of the quality management system and its implementation, with the primary aim to determine a strategy to improve the quality culture in the organisation. If the required support is received from the FKMSA employees through their participation, there will be buy-in towards planned quality initiatives and gap closure.

1.2 BACKGROUND OF THE STUDY

1.2.1 Overview of FKMSA

Fresenius Kabi Manufacturing South Africa, as it is known today, emerged late in 2010, when Fresenius Kabi AG approved the application for the change of name. The main reasons for the name change were to link the local manufacturing part of the business to its marketing company.

FKMSA provides and maintains a working environment that encourages the entrepreneurial spirit in all employees with a view to achieving their full potential and maximising their growth and that of the organisation; also to increase its market competitiveness while satisfying the needs of employees, suppliers and customers and building long-standing relationships amongst colleagues, suppliers and customers.

Further, included in its track record and a committed, skilled and experienced workforce, is its ability to always stay abreast of the most modern technological and

product developments. This can largely be attributed to its world class research and developments through its multinational parent company. The Port Elizabeth plant has recently added freeflex® lines for further improvement of capacity, cost-efficiency and quality throughout the facility. Freeflex ® is a new generation flexible infusion bag that meets the demands of evolving infusion therapy. The components used in Freeflex technology are made from PVC free material without plasticisers, adhesives or latex. It is also designed to minimise its impact on the environment.

1.2.2 The importance of quality at FKMSA

The organisation's aim is to be the preferred supplier of quality critical care products to Fresenius Kabi South Africa Marketing Unit and other third party companies, for use by critically ill patients. The facility is tasked with the production of standard solutions, as well as hormonal and non-hormonal I.V. drugs and aseptic products for the Fresenius Kabi South Africa portfolio.

Due to the nature of the products manufactured in this plant, quality is extremely important in every step of production. Hence, quality management system has been implemented to ensure that all processes are carried out in line with good management practice (GMP) and ISO.
All quality policies are outlined in the quality manual and standard operating procedures. The facility has been approved for manufacturing of sterile products by the medicine control council (MCC) and the MCC performs yearly audits to ensure that quality standards are maintained.

1.3 RATIONALE FOR THE STUDY

Quality initiatives at FKMSA are primarily driven by the quality control departments. This is despite a comprehensive company quality control policy and a highly recognised quality management system. There is limited support for quality control initiatives by the majority of site employees. This research is being conducted to determine employee perceptions of quality in order to provide insight into the reasons why the level of support shown by most employees is not ideal.

This research provides information on how to create support for quality initiatives from employees outside the quality control department. The information that is obtained from this research will provide insight into the current quality culture and direction on how to achieve a proactive and self-directed quality culture. This research hopes to provide an understanding as to why the quality of product, service and process is not 100% correct the first time.

The feedback on employee perceptions obtained from the research will be utilised to determine a strategy to improve the quality culture on the site.

1.4 OBJECTIVE OF THE STUDY

1.4.1 Primary objective

The primary objective of the study is to assess the employees understanding of quality and the related risks in the pharmaceutical industry. The research will highlight the level of quality awareness in the organisation by determining employee perceptions of quality at FKMSA. The research will also evaluate the level of awareness, involvement and responsibility taken by each employee in each department to ensure that high quality standards are maintained in the entire organisation.

1.4.2 Secondary Objectives

Secondary objectives of the study are:

To ascertain a quantitative measurement of employees overall perceptions of quality;

To ascertain employee perceptions in terms of awareness of the quality system and the organisation's quality policy;

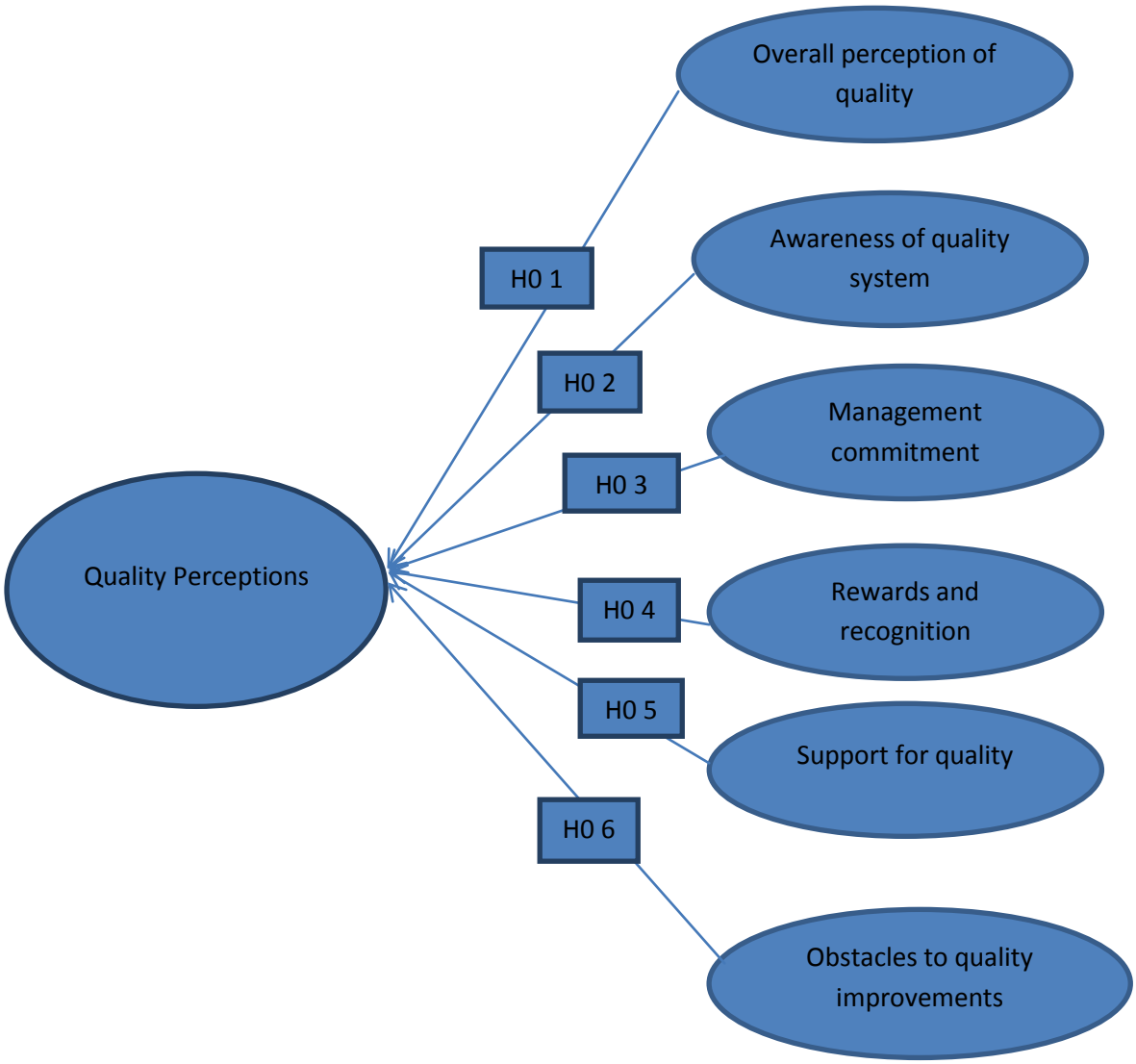
To determine employee perceptions of management's commitment to quality;

To assess employee perceptions of reward and recognition for support of quality;

To determine the perception of employees who are not part of management and their support towards quality initiatives;

To determine limitations that can obstruct the success of quality initiatives;

Figure: 1.1 Conceptual framework model to assess quality perceptions



Source: Adapted from Naidu (2007)

1.5 THE NULL HYPOTHESES

The following null hypotheses are formulated:

H01. There is no significant relationship between the perceptions of quality and overall organisation quality.

H02. There is no significant relationship between the perceptions of quality and the awareness of quality systems.

H03. There is no significant relationship between quality perceptions and management commitment.

H04. There is no significant relationship between quality perceptions and rewards and recognition.

H05. There is no significant relationship between quality perceptions and the support of quality.

H06. There is no significant relationship between quality perceptions and obstacles to the improvement of quality.

1.6 LIMITATIONS TO STUDY

Some limitations which could have an influence on the outcomes of this study are listed below:

- Data collection was completed by means of a self-completed, closed response questionnaire and there was no control over the response rate
- The study was limited to FKMSA Port Elizabeth employees
- Due to a number of external audits taking place in the organisation, employees might link the completion of the questionnaire to the company's audit preparation.

1.7 RESEARCH METHODOLOGY

This quantitative study involved responses that focused on employee perceptions of quality in their work environment. Primary data was gathered using a self – administered, closed response questionnaire that was designed around both the primary and secondary research objectives and involved twenty one questions.

A five-point scale ranging from "strongly disagree" on one end to "strongly agree" on the other, was used to measure the attitudes of respondents. The responses were then coded to facilitate analysis of this non-numerical category data between the different departments and job functions that existed on the manufacturing site.

The data analysis was quantitative in nature and involved the use of descriptive (frequency tables and bar graphs) as well as inferential statistical measures (Cronbach alpha).

The study was conducted in June 2013 by way of a census on the full, permanent employee complement on the manufacturing site, consisting of approximately 506 employees.

1.8 STRUCTURE OF THE STUDY

Chapter 1 provides an introduction to the study. The rationale for the study is presented together with the research objectives and summary of the research methodology. An overview of the organisation and industry where the study was conducted is also presented. The structure of the dissertation is also clarified in this chapter.

Chapter 2 is a critical review of related literature on the definitions, principles and practices with respect to quality, QMS and related regulatory requirements. This chapter further reviews perception, management commitment, and rewards.

Chapter 3 describes the research methodology. This includes the research design, data collection, data analysis, validity, reliability, bias and ethical considerations.

Chapter 4 presents the research findings, analysis of the data and interpretations of these results in line with the theory discussed in the literature review chapter.

Chapter 5 presents the overall conclusions obtained during the research, recommendations for FKMSA and scope for further research.

1.9 CONCLUSION

Chapter 1 introduces the background to the study and the organisation selected for this research. It also gives clarity on the research variable to be used in the study. Having introduced the study in Chapter 1, the next chapter outlines a review of the literature collected on the various topics related to the study and includes a discussion of QMS, quality assurance principles as well as various employee perception concepts linked to the study.

CHAPTER 2- LITERATURE REVIEW

2.1 INTRODUCTION

In chapter one the researcher outlined the background to the study and the research process that will be followed. This chapter will review literature on QMS, quality assurance principles and related aspects on perception, including leadership commitment, culture and reward and recognition. In addition, the definitions of quality and perception that are regarded as suitable for this study are explained.

2.2 DEFINING QUALITY ASSURANCE

According to (ISO 9001:2008) quality assurance forms an integral part of QMS and it is aimed at providing confidence that quality requirements will be achieved. It ensures that all the planned and systematic activities implemented within the quality system can be demonstrated to provide confidence that a product or service will fulfil the requirements of quality. Hence quality assurance is mainly focused on planning and documenting manufacturing processes to assure quality throughout the entire procedure (Zolner, 2008).

In the pharmaceutical industry quality assurance is defined as the aspect of management function that determines and implements the quality policy, which is the overall intention and direction of an organisation regarding quality, as formally expressed and is authorised by top management Storey, Briggs, Jones & Russell (2000).

Kelemen (2003) identifies the basic elements of quality management as including the following:

- An appropriate infrastructure or quality system, encompassing organisational structure, procedures, processes and resources; and
- Systematic actions necessary to ensure adequate confidence that a product will satisfy given requirements for quality;

He then concluded that the combination of these actions is termed quality assurance.

According to the World Health Organisation (WHO, 2007), quality assurance appropriate to the manufacture of pharmaceutical products should ensure that the following aspects of quality are included in the quality management system:

- Pharmaceutical products are designed and developed in a way that takes into consideration the requirements of good manufacturing practice (GMP) and good laboratory practice (GLP) principles;
- Production and control operations must be clearly defined in a written procedure;
- Managerial responsibilities must be specified in job descriptions;
- Appropriate measures are in place for the manufacture, supply and use of the correct starting and packaging materials;
- All approved quality controls on starting materials, intermediate products and bulk products and other in-process controls, calibrations and validations are performed as per written procedures;
- The finished product is correctly processed and checked, according to the defined procedures;
- Pharmaceutical products are not released or supplied before the authorised persons have certified that each production consignment has been produced and controlled in accordance with the requirements of the marketing authorisation and any other regulations relevant to the production, control and release of pharmaceutical products;
- Satisfactory arrangements exist to ensure, as far as possible, that the pharmaceutical products are stored by the manufacturer, distributed and subsequently handled so that quality is maintained throughout their shelf-life;
- There is a procedure for self-inspection and quality audit that regularly appraises the effectiveness and applicability of the quality assurance;
- Deviations or non-conformances are reported, investigated and recorded;
- There is a system for approving changes that may have an impact on product quality;
- Regular evaluations of the quality of pharmaceutical products should be conducted with the objective of verifying the consistency of the process and ensuring its continuous improvement.

The key quality assurance requirements that are essential in the production of sterile products are described below (Kastango & Douglass, 2001);

- Employees must be capable and competent to perform their roles and responsibilities;
- Starting materials used in manufacturing must comply with release specifications;
- Critical processes must be validated to ensure that procedures used consistently result in the expected quality of the finished product;
- The production environment must be suitable for its objective;
- Standard operating procedures for investigating and correcting failures or deviations in the preparation or testing of a product must be followed and recorded; and
- Quality control functions and decisions must be adequately separated from those of production.

The WHO (2008) states that the pharmaceutical manufacturer must assume responsibility for the quality of the products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorisation, and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment of employees in different departments and at all levels within the organisation, the company's suppliers and the distributors.

To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating GMP and quality control. It should be fully documented and its effectiveness monitored. All parts of the quality assurance should be adequately staffed with competent personnel and should have suitable and sufficient premises, equipment and facilities.

2.3 QUALITY MANAGEMENT SYSTEMS

According to FDA (2009), the quality management system ensures that the manufacturer's objective of providing the customer with a quality drug product is achieved. Hence an effectively implemented quality system will prevent the number of recalls, returned or damaged products and defective products entering the marketplace.

The QMS in the pharmaceutical industry must be integrated with GMP regulations such as ISO 9001: 2008. With the globalisation of this sector and the increasing prevalence of drug and biologic device combination products, the convergence of quality management principles across different regions and among various product types is important. According to the *American society for quality* (2007), when quality systems are integrated with the manufacturing process, product knowledge and the use of effective risk management practices, it can control different types of changes to facilities, equipment and processes without the need for prior approval regulatory submissions.

A quality management system can therefore provide the needed structure for implementing quality by building in quality, from the research and development phase throughout the products life cycle, continually improving the product manufacturing process. A quality system adopted by a manufacturer can be designed to be suitable for their specific environment (Enders, 2000).

2.3.1 Quality by design (QBD) and product development

According to Patil and Pethe (2013), quality by design means designing and developing a product and associated manufacturing processes that will be used during product development to ensure that the product consistently attains a predefined quality until the end of the manufacturing process. Abraham (2004) agrees that quality by design, in combination with a quality management system, provides a sound framework for the transfer of product knowledge and process

understanding, from drug development to the commercial manufacturing processes, and for post development changes and optimisation.

ICH Q8 (2006) defines quality as the suitability, of either a drug substance or drug product for its intended use. This term includes such attributes as identity, strength and purity. Pharmaceutical QBD is a systematic, scientific, risk based, holistic and proactive approach to pharmaceutical development that begins with predefined objectives and emphases product and processes understanding and process control. It means designing and developing formulations and manufacturing processes to ensure predefined product quality objectives (Menard, 2006).

QBD identifies characteristic that are critical to quality from the perspective of patients, translates them into the attributes that the drug product should possess, and establishes how the critical process parameters can be varied to consistently produce a drug with desired characteristics. In order to do this the relationship between formulation and manufacturing process variables and product characteristics are established and sources of variability identified. This knowledge is then used to implement a flexible and robust manufacturing process that can adapt and produce a consistent product over time (Gibson, 2001).

2.3.2 Quality risk management (QRM)

According to Viornery (2010), QRM is a systematic process used for the assessment, control, communication and review of risks to the quality of the pharmaceutical product. It can be applied both proactively and retrospectively. QRM is a valuable component of an effective quality systems framework. It can help guide the setting of specifications and process parameters for drug manufacturing, assess and mitigate the risk of changing a process or specification, and determine the extent of discrepancy investigations and corrective actions.

Nasr (2004) added that QRM is a key enabler for the development and application of quality by design. During development, it enables resources to be focused on the perceived critical areas that affect product and process. It is one of the tools that provide a proactive approach to identifying, scientifically evaluating and controlling

potential risks to quality. It also facilitates continual improvement in the product and process performance throughout the product life cycle.

Mills (2010) identified the four primary principles of QRM as the following:

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately linked to the protection of the patient;
- QRM should be dynamic and responsive to change;
- The level of effort, formality and documentation of the QRM process should match with the level of risk; and
- The capability for continual improvement and enhancement should be embedded in the QRM process.

QRM forms an integral part of the QMS at FKMSA, the organisation currently focuses on unplanned risk assessments and the risk analysis tool used is the FMEA. The organisation is moving towards documenting and investigating both planned and unplanned quality risks, as this has become the focus of most regulators. The organisation is also moving towards more team and scientific based risk analysis.

2.3.3 Corrective and preventive action (CAPA)

CAPA is a widely utilised GMP regulatory concept that focuses on investigating, understanding and correcting discrepancies while attempting to prevent their recurrence. Immel (2006) discusses quality system CAPA models using a number of intergraded concepts, outlined below:

- Remedial corrections of an identified problem;
- Root cause analysis with corrective action to help understand the cause of the deviation and potentially prevent recurrence of a similar problem;
- Preventive action to avoid recurrence of a similar potential problem; and
- The manufacturer must establish and maintain procedures for implementing corrective and preventive action.

CAPA is an important part of a QMS and guides the organisation in effective corrective and preventative actions. At FKMSA the CAPA tool is mostly used as a

consequence of deviation, thus corrective and preventive measures are investigated and implemented using the CAPA tool.

2.3.4 Change control

Change control focuses on managing change to prevent unintended non conformities (FDA, 2010). The GMP regulations provide for change control primarily through the assigned responsibilities of the quality control unit. Certain major manufacturing changes (for example changes that alter specifications, a critical product attribute or bioavailability) require prior regulatory approval.

Effective change control activities are key components of any QMS. This allows manufacturers to make changes subject to the regulations based on the variability of materials used in manufacturing and process improvements resulting from knowledge gained during a product's lifecycle.

According to (FDA 21 CFR Part 11), the following are the key benefits of intergrading change control in the QMS:

- Structured and consistent approach towards managing change;
- Documenting the details of change;
- Routing of change requests to appropriate and competent individuals for approvals;
- Documentation of change approvals and implementation;
- Maintenance of change history and easy retrieval of information;
- Tracking changes effectively and providing an audit trail; and
- Demonstrate compliance to regulations.

2.3.5 Deviations

Deviation is a non-compliance with an established standard. In this regard the European guide to good manufacturing practice (2010) states that any deviation from the approved requirements and procedures must be documented and explained.

Bredehoeft and O' Hara (2009) state that a well-designed and implemented deviation management (DM) system offers a mechanism for obtaining critical quality data in a

timely manner to enable quick response to failures, early warning of potential failures and redeployment of resources to departments in need of quality support. It is one of the most valuable tools available to management to help maintain a state of control. To be successful, the DM process must work for the organisation rather than the organisation working for the system. It must be designed to perform at the correct level to meet the organisation's needs and to deliver optimal results. This requires incorporating quality risk management principles, prioritisation and an understanding of conflicting interests among the consumer, regulatory agencies and the business.

According to (ICH Q10 2007), when a deviation is identified, a subject matter expert should evaluate and assess the risk associated with the incident. Risk is commonly defined as the combination of the probability of occurrence of harm and the severity of that harm. Deviations range in degree of criticality or potential risk; many are minor and can be corrected on the spot while others present a higher safety risk and require more work. Therefore, deviations must be handled in a manner that is proportionate with the level of risk. Higher risk deviations, that are a risk to the patient, (that is health or safety), risk to the business (for example loss of product or production) and regulatory risk (for example warning letters, recalls) may require immediate or containment actions to stop the deviation from continuing, to contain the damage or to gain control of all potentially affected products.

The importance of performing a good root cause analysis (RCA) cannot be overstated because the actions taken to correct or prevent the deviation from recurring are directly related to and depend on finding the right cause. However, investigators often fail to dig deeply enough to find the cause and consequently apply the wrong corrective action, thereby risking recurrence of the problem. By prematurely ending the search, investigators may incorrectly focus on placing blame on an individual involved or providing unneeded retraining rather than seeking an opportunity to design safety into a process (ICH Q9, 2005).

CAPA plans require that individual tasks and deliverables, timelines, roles and responsibilities be documented. This provides a mechanism for tracking completion of all activities associated with the action plan. Progress reports should be sent to

the affected department managers and the quality unit timeously to ensure that timelines are met and any problems are addressed in time. If timelines cannot be met, justification for the delay should be documented and forwarded to the quality unit for review and concurrence.

The benefits derived from a well thought out corrective action based on in-depth root cause analysis are multiple and include the following (ICH Q9, 2005):

- prevention of deviations from recurring and prevention of potential deviations from occurring;
- reduction in recalls and market withdrawals;
- reduced safety and regulatory risk;
- increased customer satisfaction resulting from consistently produced quality products;
- redeployment of resources from resolving problems of other projects and commitments; and
- Increased employee satisfaction (reduced frustration) in resolving problems in an efficient and effective manner.

The below diagram illustrates the integration between the different elements of the QMS system at FKMSA.

Figure 2.1: Deviation process

Source: Bredehoeft and O' Hara (2009)

2.3.6 Role of measuring QMS progress

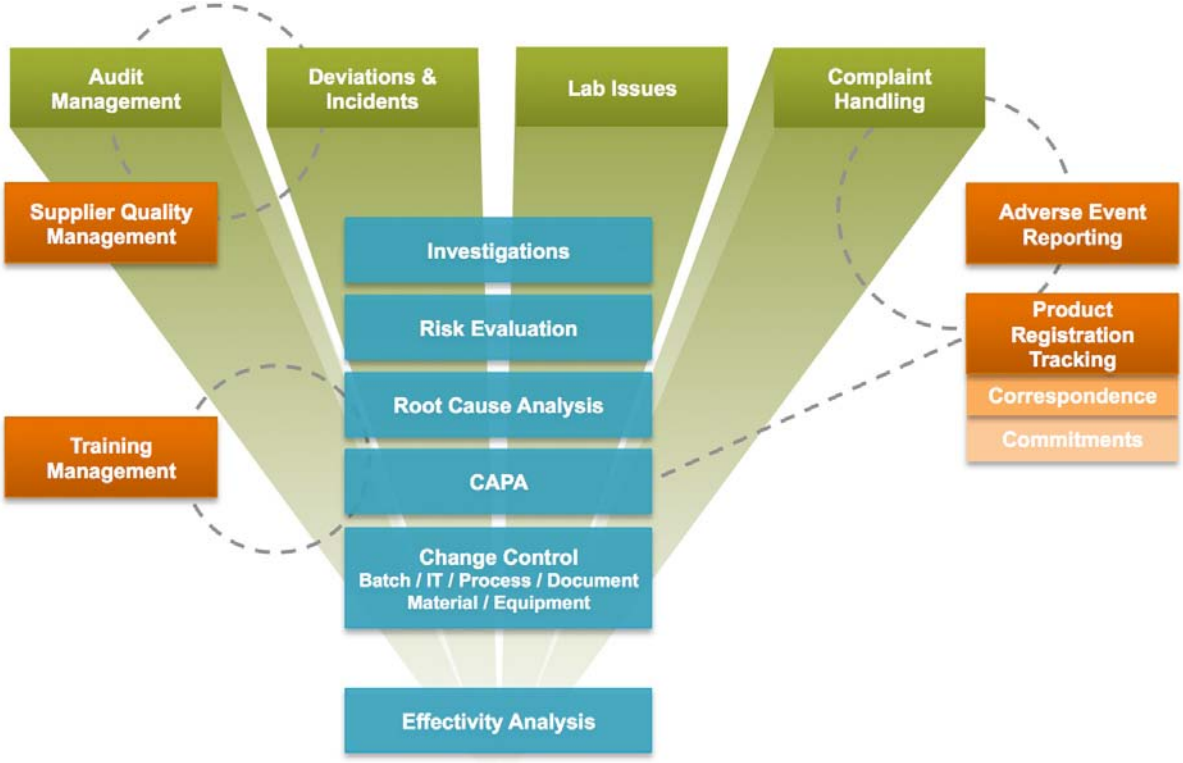
QMS do not stop with development and implementation; they also have to be monitored to determine the relevance and benefits they provide to the organisation. Measuring QMS progress is a form of evaluation to determine whether the system is still benefiting the organisation.

According to Cummings and Worley (2001), this stage involves measuring organisational processes against quality standards. Knowing and analysing the competition's performance are essential for any QMS effort because it sets minimum standards of costs, quality and service and ensures the organisation's short term position in the industry. He further says that for the longer term analytical efforts concentrate on identifying world-class performance, regardless of industry and creating benchmarks across all industries.

The different components of quality management discussed in this section are applicable and are regulatory requirements for all pharmaceutical manufacturers. FKMSA utilises both an electronic and manual system to control and integrate the company's QMS. The organisation has a long term, continual improvement plan to move all quality management aspects to an electronic system.

The diagram below shows all the different QMS aspects measured and monitored at FKMSA. Monthly QMS trending and feedback is conducted by all department managers.

Figure 2.2: Integration of QMS



Source: Adapted from Bredehoeft and O' Hara (2009)

2.4 SUPPORT FOR QUALITY

Appropriate allocation of resources is an important element to creating a robust quality system and to complying with the CGMP regulations.

Under a robust quality system, sufficient resources should be allocated for quality system and operational activities. Under the model, senior management, or a designee, should be responsible for providing adequate resources for the following:

- To supply and maintain the appropriate facilities and equipment to consistently manufacture a quality product;
- To acquire and receive materials that are suitable for their intended purpose;
- For processing the materials to produce the finished drug product; and

- For laboratory analysis of the finished drug product, including collection, storage, and examination of in-process, stability, and reserve samples.

Under a quality system, continued training is critical to ensure that the employees remain proficient in their operational functions and in their understanding of CGMP regulations. Typical quality systems training should address the policies, processes, procedures, and written instructions related to operational activities, the product/service, the quality system, and the desired work culture (e.g., team building, communication, change, behaviour). Under a quality system (and the CGMP regulations), training should focus on both the employees' specific job functions and the related CGMP regulatory requirements.

Under a quality system, managers are expected to establish training programs that include the following:

- Evaluation of training needs;
- Provision of training to satisfy these needs;
- Evaluation of effectiveness of training; and
- Documentation of training and/or re-training.

When operating in a robust quality system environment, it is important that managers verify that skills gained from training are implemented in day-to-day performance.

Under a quality system, the technical experts (e.g., engineers, development scientists), who have an understanding of pharmaceutical science, risk factors, and manufacturing processes related to the product, are responsible for defining specific facility and equipment requirements.

Under the CGMP regulations, the quality unit (QU) has the responsibility of reviewing and approving all initial design criteria and procedures pertaining to facilities and equipment and any subsequent changes.

Under the CGMP regulations, equipment must be qualified, calibrated, cleaned and maintained to prevent contamination.

2.5 AWARENESS OF QUALITY SYSTEMS

According to (ICH Q10 2007), senior management should establish a quality policy that describes the overall intentions and the company's quality direction. The quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.

The quality policy should be communicated to and understood by personnel at all levels in the company. The quality policy should be reviewed periodically for continuing effectiveness.

According to FDA (2009) Management should ensure that appropriate communication processes are established and implemented within the organisation. Communication processes should ensure the flow of appropriate information between all levels of the company.

Communication processes should ensure the appropriate and timely escalation of certain product quality and pharmaceutical quality system issues.

2.6 EMPLOYEE PERCEPTION

This section will discuss employee perception which is a very important part of the research. The section will define perception and discuss factors that affect employee perception.

2.6.1 Defining Perception

According to (Robbins, Lauver, Le, Davis, Langley & Carlstrom, 2004) perception can be defined as a process by which individuals organise and interpret their sensory impressions in order to give meaning to their environment. Perception is not necessarily based on reality, but is merely a perspective from a particular individual's point of view. In dealing with the concept of organisational behaviour, perception becomes important because people's behaviour is based on their perception of reality, not on reality itself; the world as it is perceived is the world that is

behaviourally important. Luthans, (2003) adds that perception is an important mediating cognitive process through which persons make interpretations of the stimulus or situation they are faced with.

Employee perception is a factor that can make a huge difference in the quality of the workplace. Pareek (2001) agrees that when employees view the employer, their work and their relationships within that workplace as being positive, there is a good chance the employee will be productive and will place more focus on the organisational goal of producing high quality products. Negative perceptions of the company and the working environment can cause lack of interest in the organisation and hence less focus placed on producing quality products.

This study will focus on determining the perception of quality produced in the different departments in the organisation and its impact on the quality of the products manufactured in this facility.

2.6.2 Factors influencing employee perception

Besterfield, Besterfield-Michna, Besterfield, & Besterfield-Sacre (2003) state that for most employees, a clear and concise communication within a working environment is essential for carrying out the required task. When the organisation chooses not to create channels of communication with employees that allow each party to share information with the other, chances are that employee perception of the company will be less than ideal. Lack of communication can go a long way toward setting up a mentality that breeds negativity in the workplace, opens the door for rumours to develop and can undermine the morale of even the most devoted of employees.

Robbins et al (2004) suggest factors influencing a person's perception and breaks them down into three main categories. These are:

- The situation - which may include time, work setting or social setting;
- The perceiver - may include attitudes, motives, interests, experiences and expectations; and
- The target - may include novelty, motion, sounds, size background, proximity and similarity.

Schermehorn, Hunt, & Osborn (2004) explain that perception affects employee working relationships in many ways and can have a positive or negative impact on quality. For example, based on the situation, perceiver and target may have the perception that the people they are working with are not competent and therefore they may tend to avoid working with them for fear of being held responsible for their mistakes due to incompetency, thus affecting the working relationship with team members and ultimately, the effectiveness and efficiency of the organisation.

Organisational leadership needs to become aware of the power of perception, learn what circumstances are likely to cause incorrect perceptions, learn how to manage employee perceptions to the extent possible and always approach perception as the perceiver's reality (McConnell,1994).

Quality in the pharmaceutical industry is one of the most important aspects of the day to day business and any compromise in quality can potentially lead to fatalities. It is important for FKMSA to use the correct communication channels for quality related issues and to ensure that employees will be able to accurately interpret the communication.

2.6.3 Employee Motivation

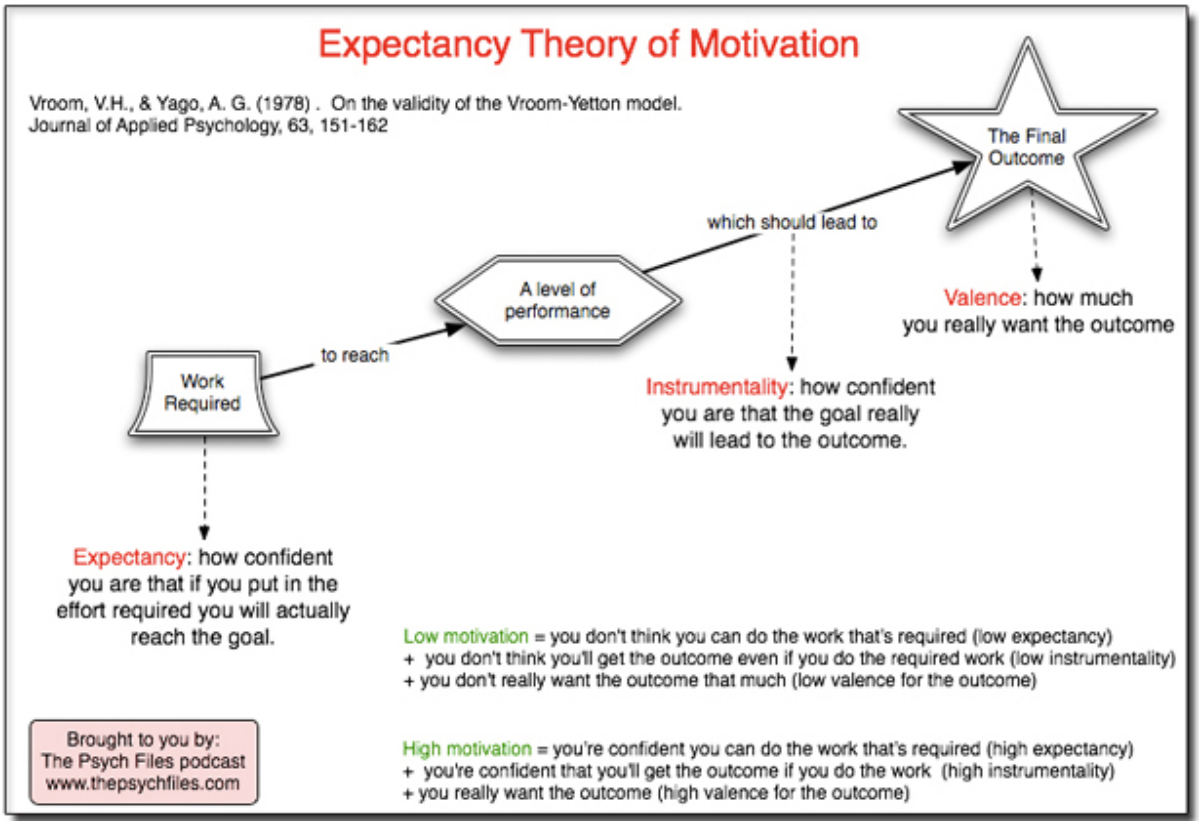
The Expectancy Theory of Motivation is best described as a process theory. It provides an explanation of why individuals choose one behavioural option over others. The theory assumes that people are motivated when they feel that whatever decision they take this “will lead to their desired outcome" (Redmond, 2010). Fang (2008) note that "Expectancy theory proposes that work motivation is dependent upon the perceived association between performance and outcomes and individuals modify their behaviour based on their calculation of anticipated outcomes". This has a practical and positive benefit of improving motivation because it can and has helped leaders create motivational programs in the workplace. Although the theory is not "all inclusive" of individual motivation factors, it provides leaders with a foundation on which to build a better understanding of ways to motivate subordinates

Expectancy theory is classified as a process theory of motivation because it emphasises individual perceptions of the environment and subsequent interactions arising as a consequence of personal expectations.

The theory states that individuals have different sets of goals and can be motivated if they believe that:

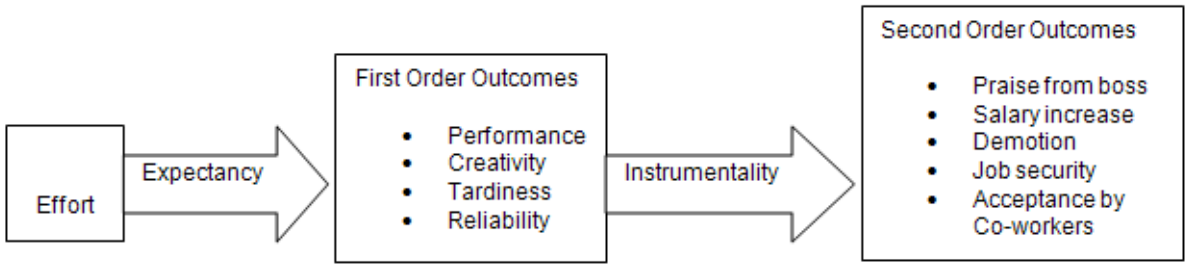
- There is a positive correlation between efforts and performance;
- Favourable performance will result in a desirable reward;
- The reward will satisfy an important need; and
- The desire to satisfy the need is strong enough to make the effort worthwhile (Lawler, Porter & Vroom, 2009).

Figure 2.3: Expectancy theory of motivation



Source: Lawler, Porter and Vroom (2009).

Figure 2.4: Expectancy theory



Source: Lamer, Porter and Vroom (2009)

Vroom (1995) also believes that increased effort will lead to increased performance; given the person has the right tools to get the work done. The expected outcome is dependent upon whether or not the person has the resources, skills and the support to accomplish the task at hand. That support may come from the organisation or simply by being given the correct information and/or tools to accomplish the work.

Motivation implies that people make decisions about their own behaviour and about what motivates them.

2.7 MANAGEMENT COMMITMENT TO QUALITY

Babakus, Yavas, Karatepe and Avici (2003) explain management commitment as the direct involvement by the highest level of leadership in a specific and critical section of an organisation. In quality, management commitment includes implementing and being members of the quality committee, formulating and establishing quality policies and objectives, allocating resources and training, overseeing implementation at all levels of the organisation and evaluating and monitoring of the outcomes.

Management commitment must be driven by a strong desire to improve the quality of the entire organisation. Carruthers & Krisjanous (2006) notes that top management must not only set the lead for the rest of the company but must also ensure that the necessary decisions and actions are taken.

Management role in quality management has been highlighted as one of the crucial requirement for a successful quality improvement implementation. According to Pheng and Jasmine (2004), the degree of support that management takes in the

implementation of a total quality environment is critical to the success of quality system implementation and the system cannot be fully implemented if there is lack of commitment from top management. Commitment of top managers in quality system implementation enables the employees to follow their direction and way of working.

2.7.1 Commitment of management “New Thinking”

Ernst and Young (1990) explore the concept of management commitment in relation to customer oriented quality thinking. They suggest that commitment moves through several stages in a sequential manner and steps are discussed below:

- Sufficient management commitment to financially support new innovative activities, meaning management is personally involved and expects significant short term results;
- Commitment of time to gain an understanding, hence management is personally involved and expects the significant short term results within the set period;
- Intellectual understanding means that no real desire to work for quality issues. Need short term benefit to justify further investment;
- Willingness to work on critical issues and to increase personal involvement that is No desire to change own behaviour;
- Desire to change one’s own behaviour meaning management does not need short-term benefits to justify the investment in time and effort. Thus placing quality ahead of quantity; and
- Completely internalised that is behaviour reflects new thinking.

The above mentioned six steps show a process of how commitment is evolved in management behaviour. Initially management wants to focus on short term benefits and then on the long term. Quality is a long term process hence to get management commitment it needs to be broken down it into small goals, which create visibility and enforce management to be commitment to provide resources and time.

To encourage a culture of quality first, management at FKMSA must have hands on approach regarding quality issues and include quality management review in their periodic review of business performance. Management must show urgency regarding quality related issues to be able get the buy-in from employees at all levels.

2.7.2 Leadership by top management

Quality leadership by top management has been highlighted and supported by many studies as the basis for effective implementation of quality system in order to achieve customer satisfaction, quality product, continuous improvement and job satisfaction (Anderson, Rungtusanatham & Schroeder 1995). For the organisation to achieve total quality, it is imperative that leadership clearly defines the quality goals or objectives, as well as treats quality as an important aspect of the business. Top management is expected to set quality as a priority while allocating adequate resources to continuous quality improvement and evaluating employees based on their performances (Minjoon, Shaohan and Hojung, 2006).

When top management is committed to quality system implementation this will enhance employee empowerment, teamwork, and training and employees job satisfaction. In a research completed by Minjoon et al. (2006) on a number of companies between the Mexican and US borders, implementing quality system management leadership was seen as an important aspect. It concluded that, significant changes can be implemented in an organisation, based on the nature of management commitment. Management commitment plays a very important role in the quality systems at FKMSA as this influences the financial recourse allocation and the employee's support of quality enhancement.

Many organisations have failed in implementing quality systems because of the reluctance of top management to delegate some authority and empower employees (Minjoon et al. 2006).This is a crucial aspect because if the managers are committed to empowering the employees, the employees will be responsible for the quality of their work and this will go a long way to enhancing continuous improvement. Top

management should demonstrate empowerment by allowing its project managers to take full responsibility and make decisions (Pheng & Jasmine, 2004).

2.7.3 Top management role in project realisation

The magnitude of a successful project depends on the level of top management commitment (Olorunniwo & Udo, 2002). Project rejections, acceptance, resistance and variation is a function of management support, thus, their involvement at all stages or levels, empowering employees where necessary and managing resources, is of paramount importance.

Olorunniwo and Udo (2002) identified three main aspects of top management support which are crucial in quality systems practice and project completions:

- Showing interest by participating in team meetings, willingness to spend time with people and listen to feedback, as well as willing to help resolve problems;
- Providing necessary resources, including training and other crucial resources;
- Providing leadership by helping to translate plan into action, regular reviewing of project programs and official commissioning of project leaders and project teams;
- They also highlight the fact that top management are expected to set the overall directions of the project by formally forming an executive steering committee to track, review and monitor quality projects.

Singh (2000) also found that a supportive management environment builds organisational commitment and job satisfaction, reduces staff turnover and enhances employee performance.

2.8 RECOGNITION AND REWARDS

According to Lawler (2003), at a minimum there are two factors that can determine the attractiveness of a reward; the first one is how much of the reward is being offered and the second is how much the person values the kind of reward being offered. Lawler (2003) also argues that the more the person values the kind of reward and the better the reward, the greater the motivational potential.

Beer et al. (1984, p. 117) argues that:

“Organisations must reward employees because, in return, they are looking for certain kinds of behaviour: they need competent individuals who agree to work with a high level of performance and loyalty. Individual employees, in exchange for their commitment, expect certain intrinsic rewards in the form of promotions, salary, fringe benefits, bonuses, or stock options. Individuals also seek intrinsic rewards such as feelings of competence, achievement, responsibility, significance, influence, personal growth and meaningful contribution. Employees will judge the adequacy of their exchange with the organisation by assessing both sets of rewards.”

Deeprose (1994, p. 26) defines reward management as:
“the process of developing and implementing strategies, policies and systems which help the organisation to achieve its objectives by obtaining and keeping the people it needs, and by increasing their motivation and commitment.”
Recognition programmes have the purpose of keeping employees motivated and productive and are seen to be effective methods of reinforcing company expectations and goals.

The report on salary survey (2003) conducted in the United States of America (USA) by the Institute of Management and Administration, provides statistics on recognition programmes. They found that:

- Recognition programmes were becoming more wide-spread, with 84% of organisations having one in place and 54% of those without any programmes reporting that they may implement one in the next 12 months;

- The number one reason for implementing a recognition programme is to create a positive work environment, followed by reinforcing positive behaviour and motivating high performance;
- Most of these programmes offered both formal and informal types of recognition. Informal programmes might include spontaneous gestures of appreciation, such as a small gift, while a more formal programme would reward both years of service and performance;
- The item most widely used as a rewards are gift certificates (61%), followed by cash (58%), office accessories (41%), and jewellery (40%);
- The success of recognition programmes is measured mainly through employee satisfaction surveys (61%). Forty seven percent (47%) gauge it by the number of nominations and forty percent by usage or participation rates;
- Information about recognition programmes is communicated through the intranet (73%), company newsletter (65%), and employee orientation (56%) and in employee handbook (35%).
- Three quarters of organisations conduct training sessions with their managers to teach them about the recognition programmes and 42% use a handbook, while 34% rely on on-line education.

The above statistics provide some interesting insight and guidelines for the establishment of a recognition programme within an organisation.

Wilson (1994) states that for a reward system to be successful it must have a positive impact on human behaviour. To attain this, rewards need to be:

- Contingent on achieving desired performance levels rather than on merely doing certain tasks;
- Meaningful and valuable to the individual;
- Based on objective and attainable organisational goals;
- Open to all and not based on competitive struggles within the workplace ; and
- Balanced between conditions in the workplace and fulfilment of individual needs and wants.

Lack of recognition has been mentioned as one of the major reasons for top talent leaving organisations and looking for employment elsewhere (Sethi & Pinzon, 1998).

Wilson (1994) makes the following suggestions for conditions that stimulate the same or related behaviour in the future:

- Employees need to know what they have done to earn the recognition and continue doing so. Performance measurement and feedback are essential for consequences to be effective in shaping desired behaviours.
- Recognition has to be meaningful to the employee. Thus the method of delivery and the source of a reward are often as important as the item, comment or activity.
- Recognition has to be earned so that employees feel that they have truly achieved some action or result. Hence, for a reward to be effective, the desired behaviour or performance needs to be within the employee's ability and control.
- Recognition has to be given in a manner that is honest, sincere and from the heart.
- Recognition must be given shortly after the achievement or contribution. Waiting for approval, deadlines or completion may reduce the impact of the reward.

Pollock (1995) also stated that leaders who recognise the power of the emotional appeal of informal forms of recognition can more easily motivate employees to higher levels of performance, often at much lower costs than monetary rewards.

2.9 LIMITATIONS TO QUALITY INITIATIVES

According to Beckford (2002), some of the limitations preventing the achievement of quality have been grouped into four main categories:

- Systems and procedures;
- Culture;
- Organisation design; and
- Management perspectives.

2.9.1 Systems and procedures

Organisations with bureaucratic processes may have fixed systems and procedures which can result in high resistance to change and adaptation. According to Carmeli, Gilat and Weisberg (2006), this can be a barrier to the implementation of a quality system. It can be recognised when members of staff use expressions, such as "we have always done it like that."

It is sufficient to say that systems and procedures must be re-designed to support the achievement of quality, with particular attention paid to the selection of performance criteria. If quality is a desired characteristic of the outputs of the organisation, it will somehow and to some degree have to be measured and must take account of the expectations of customers whether internal or external.

2.9.2 Culture

The development of a quality culture is a critical area of the achievement of quality. Beckford (2002) suggests that culture describes the values and underlying assumptions' that directs behaviour within the organisation. It is the 'values' and 'beliefs' that are the key to cultural drivers, although these may be expressed in a variety of ways. They often originate from the measurement systems and procedures, which are communicated to employees and whatever senior management considers important regarding performance. These principles become culturally meaningful and they become a part of the value system of the organisation.

According to Schein (2011), for the organisation to achieve the required quality standards, mistakes must be acknowledged and the root courses of the non-conformance are investigated and corrected and preventive action must be taken by the employees involved in the non-conformance. In some companies the realisation of mistakes is followed by the process of detection, prosecution and disciplinary action. This approach may lead to a culture where according to Deming (1986) 'fear grips everyone' and in such a situation, mistakes may not be reported. Where the mistake cannot be hidden there will be culture of blaming and shifting responsibilities.

This barrier can be overcome by recognising that mistakes are opportunities for learning, the opportunity to align a process, system, skill or behaviour to prevent re-occurrences. However, in most organisations and in many circumstances, the cause of the error can be traced to some failure in the design or execution of a process, in the training of employee or in the equipment provided for the completion of the task. These aspects should be the first focus of attention and in a quality organisation, will inhibit the use of disciplinary action.

2.9.3 Organisation design

According to Beckford (2002), the organisation chart may be seen as 'frozen out of history', revealing whom to blame when things go wrong but not showing how the organisation actually works. A number of barriers to achievement of quality can be found in this area.

The organisation can be designed in such a way that conflict between quality and other departments such as production is inherent. These conflicts are often mostly found where the quality control or quality assurance manager reports to the production manager. A structure must be created in which the quality function is independent of the production function (Evans & Dean, 2000).

2.9.4 Management perspectives

According to Beckford (2002), management perspectives refer not simply to the attitude to quality, but to the whole management ethos of the organisation as it impacts on quality. In order for an appropriate attitude to be developed to quality, it must be recognised as an issue, that is, the lack of quality in product or service must be acknowledged. Seldom is quality of product considered as a primary issue at the outset. It is essential that quality be treated as a potential part of the problem and be considered as a possible cause of the problem. Even where a company is performing well, a positive attitude to quality needs to be developed and maintained.

A further barrier to achievement of quality is a focus on short-term results only, that is, the result in a particular shift, day, week, quarter, or even year. Often, salary or wage packages and performance bonuses are related directly to current period performance. Therefore, current acceptable performance parameters are used as a reason for not addressing the issue of quality (Schein, 2011).

2.10 CONCLUSION

This chapter outlined and discussed the literature reviewed relating to quality perceptions of employees, awareness of quality systems, rewards and recognition, support for quality, and management commitment. Each concept was analysed in relation to quality perceptions. The following chapter addresses the research methodology used in establishing the measuring and data analysis methods for the study.

CHAPTER 3 - RESEARCH METHODOLOGY

3.1 INTRODUCTION

In the previous chapter, literature from different sources was reviewed in relation to employee perceptions of quality. Furthermore, the chapter discussed this by consulting a number of relevant sources relating to QMS, management commitment, rewards and recognition, support to quality and obstacles to quality improvements. In chapter three sample selection, sample size, questionnaire design, data analysis, validity, reliability and ethical considerations are discussed in detail.

3.2 THE RESEARCH DESIGN

This section of the study discusses the various parts of the research method, such as the type of research, target population, data collection and the research instrument.

3.2.1 Type of research

According to Charoenruk (2000), states that when commencing research a starting point is to try to what kind of data needs to be collected for the research undertaken. There are two broad approaches, namely qualitative and quantitative research.

Qualitative research refers to inductive and subjective methods and is used to interpret, understand, describe and develop a theory on a phenomena or setting. It is a systemic, subjective approach used to describe life experiences and give them meaning. It is mostly associated with words, language and experiences rather than measurements and statistical analysis (Bernard, 1995). It generally seeks to understand a given research problem or topic from the perspectives of the local population it involves. This type of study is especially effective in obtaining culturally specific information about the values, opinions, behaviours and social contexts of particular populations.

According to Denzin and Lincoln (2000), while findings from qualitative data can often be extended to people with characteristics similar to those in the study population, gaining a rich and complex understanding of a specific social context or phenomenon typically takes precedence over eliciting data that can be generalised to other geographical areas or populations. In this sense, qualitative research differs slightly from scientific research in general.

Quantitative research uses typical research designs where the point of interest of the research is to describe, explain and predict phenomena; it uses probability sampling and relies on larger sample sizes (Cooper & Schindler, 2006). By using particular methodologies and techniques, quantitative research quantifies relationships between different variables. In quantitative research the aim of the researcher is to study the relationship between an independent variable and a dependent variable in a population (Hopkins, 2000).

The purpose of quantitative studies is for the researcher to project research findings onto the larger population through an objective process. Data collected, often through surveys is administered to a sample or subset of the entire population, to allow the researcher to generalise when analysing the collected data. Results are interpreted to determine the probability that the conclusions found among the sample can be replicated within the larger population. Conclusions are derived from data collected and measures of statistical analysis (Creswell, 2002; Thorne and Giesen, 2002).

Leedy and Ormrod (2001) are of the opinion that quantitative research is specific in its surveying and experimentation, as it builds upon existing theories. The main aim is to establish, confirm or validate relationships and to develop generalisations that are supported by theory.

The key difference between quantitative and qualitative methods is their flexibility. Generally, quantitative methods are fairly inflexible. With quantitative methods, such as surveys and questionnaires, for example, researchers would ask all participants identical questions in the same order (Lichtman, 2006). The response categories

from which participants may choose are “closed-ended” or fixed. The advantage of this inflexibility is that it allows for meaningful comparison of responses across participants and study sites. However, it requires a thorough understanding of the important questions to ask, the best way to ask them and the range of possible responses.

Qualitative methods are typically more flexible; that is, they allow greater spontaneity and adaptation of the interaction between the researcher and the study participant. For example, qualitative methods ask mostly “open-ended” questions that are not necessarily worded in exactly the same way with each participant. With open-ended questions, participants are free to respond in their own words and these responses tend to be more complex than simply “yes” or “no” (Lichtman, 2006).

With qualitative methods, the relationship between the researcher and the participant is often less formal than in quantitative research (Leedy & Ormrod, 2001). Participants have the opportunity to respond more elaborately and in greater detail than is typically the case with quantitative methods. In turn, researchers have the opportunity to respond immediately to what participants say by tailoring subsequent questions to information the participant has provided.

It is important to note, however, that there is a range of flexibility among methods used in both quantitative and qualitative research and that flexibility is not an indication of how scientific a method is. Rather, the degree of flexibility reflects the kind of understanding of the problem that is being pursued using the method.

The following table outlines some characteristics of both quantitative and qualitative research.

Table 3.1: Comparing quantitative and qualitative research

	Quantitative	**Qualitative**
Aim	The aim is to count things in an attempt to explain what is observed.	The aim is a complete, detailed description of what is observed.

Purpose	Generalising ability, prediction, causal explanations	Contextualisation, interpretation, understanding perspectives
Scientific Method	Deductive The researcher test hypotheses and theory with data	Inductive The researcher creates new hypotheses and theory based on data collected during the study
Tools	Researcher uses tools, such as surveys, to collect numerical data.	Researcher is the data gathering instrument
Variables	Specific variables studied	Study of the whole, not variables.
Data collection	Structured Output Data is in the form of numbers and statistics	Unstructured Data is in the form of words, pictures or objects
Form of Data Collected	Quantitative data based on precise measurements using structured and validated data-collection instruments.	Qualitative data, such as open- ended responses, interviews, participant observations, field notes and reflections.
Sample	Usually a large number of cases representing the population of interest. Randomly selected respondents.	Usually a small number of non-representative cases. Respondents selected on their experience.
Objective/ Subjective	Objective – seeks precise measurement and analysis	Subjective - individuals' interpretation of events is important
Researcher role	Researcher tends to remain objectively separated from the subject matter	Researcher tends to become subjectively immersed in the subject matter.
Analysis	Statistical	Interpretive
View of human behaviour	Behaviour is consistent and predictable	Behaviour is situational, social and continually changes

Source: Johnson and Christensen, 2008; Lichtman, 2006

The primary research objective of the study was to determine employee perceptions of quality at FKMSA. The research looks at understanding employee attitudes towards quality and how it influences their perceptions by utilising specific measurements and statistics. According to Sekaran and Bougie (2010), quantitative research relies on deductive reasoning and makes use of a variety of quantitative analysis techniques that range from providing simple descriptions of the variables involved, to establishing statistical relationships among variables through statistical modelling

This study is a quantitative research study that involved the collection of data through a questionnaire distributed to all employees in the company. The researcher was then able to action a statistical analysis and interpretation of data and draw conclusions based on employee perceptions of quality.

3.2.2 Target Population

According to Young (2001), descriptive research includes surveys and fact finding enquiries of different kinds. The major purpose of descriptive research is to describe the state of affairs as it exists at present. The main characteristic of this method is that the researcher has no control over the variables and can only report what has happened or what is happening. This includes attempts by researchers to discover causes even when they cannot control the variables. The methods of research utilised in descriptive research are survey methods of all kinds, including comparative and correlation methods. In analytical research, on the other hand, the researcher has to use facts or information already available and analyse these to make a critical evaluation of the material.

According to Auberbach and Silverstein (2003), descriptive research attempts to describe, explain and interpret conditions of the present or “what is’. The purpose of a descriptive research is to examine a phenomenon that is occurring at a specific place and time. It is concerned with conditions, practices, structures, differences or relationships that exist, opinions, held processes that are going on or trends that are evident. It utilises collecting data to determine whether and to what extent, a relationship exists between two or more quantifiable variables.

For this study, data was collected from 506 employees out of whom 64 % were permanent and 36% part time at the time of the research (during June 2013). Questionnaires were distributed to all employees. The total site population formally reflected on the Human Resources database was 506 employees during the time of the study. However, at the time of the research, some employees were unavailable due to a wide range of reasons including approved annual leave.
This then reduced the population to 404 personnel during the data collection period. This population was further categorised into ten different work departments and ten different job grades within the framework of the questionnaire.

3.2.3 Data collection

According to Finn and Jacobson (2008), quantitative data collection methods rely on random sampling and structured data collection instruments that fit diverse experiences into predetermined response categories. They produce results that are easy to summarize, compare and generalise.

Quantitative research is concerned with testing hypotheses derived from theory and/or being able to estimate the size of a phenomenon of interest. Depending on the research question, participants may be randomly assigned to different categories (Russ-Eft & Preskill, 2001). If this is not feasible, the researcher may collect data on participant and situational characteristics in order to statistically control their influence on the dependent, outcome or variable. If the intent is to generalise from the research participants to a larger population, the researcher should employ probability sampling to select participants.

According to Finn and Jacobson (2008), usual quantitative data collection approaches includes the following:

- Experiments and/or clinical trials;
- Observing and recording well-defined events (such as, counting the number of patients waiting in emergency at specified times of the day);
- Obtaining relevant data from management information systems; and

- Administering surveys with closed-ended questions.

Below is a table listing the advantages and disadvantages of data collection tools used in quantitative research.

Table 3.2: Advantages and disadvantages of data collection tools

Information Collection Tools	Advantages	Disadvantages
Observation	Collect data where and when an event or activity is occurring. Does not rely on people's willingness to provide information. Directly see what people do rather than relying on what they say they do.	Hawthorne effect – people usually perform better when they know they are being observed. Does not increase understanding of why people behave the way they do.
Document Review	Good source of background information. Provides a "behind the scenes" look at a program that may not be directly observable. May bring up issues not noted by other means.	Information may be inapplicable, disorganised, unavailable or out of date. Could be biased because of selective survival of information. Information may be incomplete or inaccurate. Can be time consuming to collect, review and analyse many documents.

Surveys and Questionnaires	Administration is comparatively inexpensive and easy even when gathering data from large numbers of people spread over wide geographic area. Reduces chance of researcher bias because the same questions are asked of all respondents. Many people are familiar with surveys. Some people feel more comfortable responding to a survey than participating in an interview. Tabulation of closed-ended responses is an easy and straight forward process.	Survey respondents may not complete the survey resulting in low response rates. Items may not have the same meaning to all respondents. Size and diversity of sample will be limited by people's ability to read. Given lack of contact with respondent, never know who really completed the survey. Unable to probe for additional details. Good survey questions are hard to write and they take considerable time to develop.
Town Hall Meetings and Other Large Group Events	Can gather large amount of data at one time. Allows respondents to describe the issues that are important to them. Provides a venue where people can build on each other's knowledge.	Organising the event takes time and resources. Definitely need to have a draw to get people to attend in the form of incentives. Need to have access to people with good facilitation skills.
Case Studies	Fully depicts people's	Usually time consuming to

	experience in program input, process and results. Powerful way of portraying program to outsiders.	collect information, organise and analyse it. Represents depth of information rather than extensiveness.
Illustrated Presentations – Photo Voice, Power Voice	Fun to do and easier to get people involved because it does not seem too formal. Especially useful as a way to get people of different cultures involved or people who are more visual than verbal. Powerful way to represent data.	Takes some technological skill/expertise to prepare the presentation. Need to have good facilitation skills given that these methods are group work processes. May not speak to stakeholders who prefer more quantitative approach to data collection.

Source: Pruitt, Chapin and Rugeley (2009).

3.2.4 Sampling

According to Neuman (2005), sampling is the process of selecting a portion of the population to represent the entire population. The population should be selected based on what best suits the research question.

The foremost objective of quantitative research is to generalise. In every quantitative research, it may not be possible for the researcher to study the whole population of interest. To get information about population of interest and to draw inferences about the population, researchers use a sample which is a subgroup of the population (Lind et al. 2008).

By using a sample the researchers save lot of time and resources, get more detailed information and they are able to get information which may not be available otherwise (Bluman, 2009). Although there are a number of sampling methods available, one's choice is guided by the nature of study and the specific research questions and hypotheses. Researchers can select from broad categories of probability and non-probability samples.

According to Ingham-Broomfield (2008), the probability sampling method is any method of sampling that uses some form of random selection. In order to employ the random selection method, the researcher must set up a process or procedure that assures that the different units in the population have equal opportunity of being chosen.

The following are probability sampling methods available to a researcher:

- Simple random sampling is when the researcher selects a sample at random from the sampling frame using either a random number table manually or on computer or by an online number generator (Saunders et al., 2009).
- In systematic sampling, a researcher begins sampling with a random selection of an element in the range of 1 to k and then every kth element in the population is selected as sample (Cooper & Schindler, 2006). The kth element or skip interval is calculated as:
  k = skip interval = population size/sampling size;
- Stratified random sampling involves the process of stratification (different strata are made on the bases of different factors, such as life stages, income levels, management level and so forth) and a random sample is then drawn from each stratum (Sekaran & Bougie, 2010). Additionally, a stratum is standardised from within but diverse from other strata.
- In cluster sampling, population is divided into clusters (a cluster is a natural aggregation of elements in a population) and then randomly some clusters are drawn from the group. In a selected cluster, all elements may be selected for study or a random sample can be further drawn from the cluster (Sekaran & Bougie, 2010).

Ingham-Broomfield (2008) warns that non-probability sampling methods are less likely to produce accurate and representative samples of the population and the results cannot be used to generalise about the population. It is generally used when it is not possible or not advisable to use probability sampling.

The following are non-probability sampling methods available to researchers:

- In convenience sampling a sample of units or people is obtained, who are most conveniently available to the researcher (Zikmund, 2000);
- Judgment sampling is where the researcher utilises his personal judgment to select cases that will best answer the research questions and meet the research objectives (Saunders et al., 2009);
- Quota sampling is similar to stratified sampling but here, the selection of cases within strata is purely non-random (Barnett, 1991);
- Snowball sampling, also known as reputational sampling, is based on the idea of a rolling snowball where one or few people are initially sampled and then the sample spreads out on the basis of links to the initial group (Neuman, 2005).

This study used simple random sampling to select the employees for the study. The list of employees was retrieved from the human resource data base and questionnaires were distributed to all employees available on site.

3.2.5 The research instrument

Saunders et al (2003) refer to a questionnaire as a general term to include all techniques of data collection in which each respondent is asked to respond to the same set of questions in a set order. The research instrument used in this study is a survey questionnaire that gathered primary data from the target population. This data involved employee perceptions of quality using a self-administered, closed-ended questionnaire that was designed around the core research objectives (Naidu, 2008).

3.2.5.1 The questionnaire

Designing the research questions is a very important stage in a quantitative research process because the questions narrow the research objective and purpose down to a set of specific questions that will ensure that accurate and appropriate data for statistical analysis is collected (Creswell, 2005).

Self-administered, close ended questionnaires were utilised to ensure that accurate information on employee perception of quality was collected from different departments and levels in the organisation.

Twenty one questions were adapted from Naidu (2007) and pretested on 10 employees from the quality and production department. The pre-test results were included in the study. The questions focused on the research objectives:

- To ascertain a quantitative measurement of employees overall perceptions of quality (questions 1, 2, 13, 17),
- To ascertain employee perceptions in terms of awareness of the quality system and the organisation quality policy (questions 3, 4, 14, 15),
- To determine employee perceptions of management commitment to quality (questions 5, 6, 19)
- To assess employee perceptions of reward and recognition for support of quality (questions 7, 8, 21),
- To determine the perception of employees who are not part of management and their support towards quality initiatives (questions 9, 10, 16),
- To determine limitations that obstructs the success of quality initiatives (questions 11, 12, 18, 20).

3.2.5.2 The rating scale

Likert scales are commonly used in questionnaires to examine participant attitudes towards a range of factors. They are a method for eliciting responses by asking

participants to assign numbers to a statement or assertion in order to measure attitudes or beliefs (Rubie-Davies & Hattie, 2012). Likert scales were developed in 1932 as the familiar five-point bipolar response that most people are familiar with today. The Likert scale is a psychometric response scale primarily used in questionnaires to obtain participant's preferences or degree of agreement with a statement or set of statements (Bertram, 2001).

Likert scales are a non-comparative scaling technique and are one-dimensional in nature. Respondents are asked to indicate their level of agreement with a given statement by way of an ordinal scale. These scales range from a group of categories asking people to indicate how much they agree or disagree, approve or disapprove, or believe to be true or false. The most important consideration is to include at least five response categories (Allen & Seaman, 2007). Most commonly seen as a 5-point scale ranging from Strongly Disagree on one end to Strongly Agree on the other with neither "Neither Agree nor Disagree" in the middle.

This study used likert scale with the following ordinal scale:

1. Strongly disagree
2. Disagree
3. Neither agree nor disagree
4. Agree
5. Strongly agree

3.2.5.3 The covering letter

The first page of a questionnaire is usually devoted to the cover letter. The cover letter is the researcher's last chance to draw participation in the research (Malhotra & Birks, 2000)

The cover letter must explain the following to the respondent:

- Why the research is being undertaken;
- Who is doing the research;
- Why is it important to respond;
- How long it will take to complete the questionnaire;
- How and when the questionnaire should be returned;

- What the contact details of the researcher are;
- Whether his/her responses will be treated confidentially.

Covering letters always provide well written reasons for participating in the study and describe what the researcher is trying to achieve with the study. It also includes clear instructions on how to complete the questionnaire. The importance of the cover letter should not be underestimated. It provides the best chance to persuade the respondent to participate in the study.

The cover letter is an essential part of the questionnaire. It will affect whether or not the respondent completes the questionnaire. It is important to maintain a friendly tone and keep it as short as possible. It provides an opportunity to persuade the respondent to complete the questionnaire. If the questionnaire can be completed in less than five minutes, this should be mentioned in the cover letter and can increase the response rate.

3.2.5.4 The pre-test

According to the Australian Bureau of Statistics (2001), pre-testing refers to a range of testing techniques used prior to field testing techniques, namely pilot test, pre-test or pre-field testing techniques aim to identify non-sample errors and to suggest ways to improve or minimise the occurrence of these errors. Types of non-sample errors include:

- Respondent biases which arise from the interpretation of the questions and the cognitive processes undertaken in answering the questions;
- Interviewer effects, arising from the interviewer's ability to consistently deliver the questions as worded;
- Mode effects, caused by the design and method of delivery of the survey instrument and the interaction effects between these;

Thus, whilst questionnaire pre-testing provides means to reduce errors by improving survey questions, it cannot eliminate all errors in survey data. There are a range of

quantitative pre-testing techniques available for survey designers to use to meet different purposes. These techniques aim to identify errors that may be introduced during the administration of the survey.

Synodinos (2003) also suggests that pre-testing involves testing the research instrument in conditions as similar as possible to the research. The purpose being not to report results, but rather to check for variances in wording of questions, lack of clarity of instructions or anything that could obstruct the instrument's ability to collect data in an economical, systematic and accurate manner.

Czaja (1998) agrees that pre-tests should be conducted systematically, with potential respondents and using the same method of administration. The respondents can be selected by probability or convenience sampling and the number of completed questionnaires is usually between 20 and 70.

3.2.5.5 Distribution of questionnaires

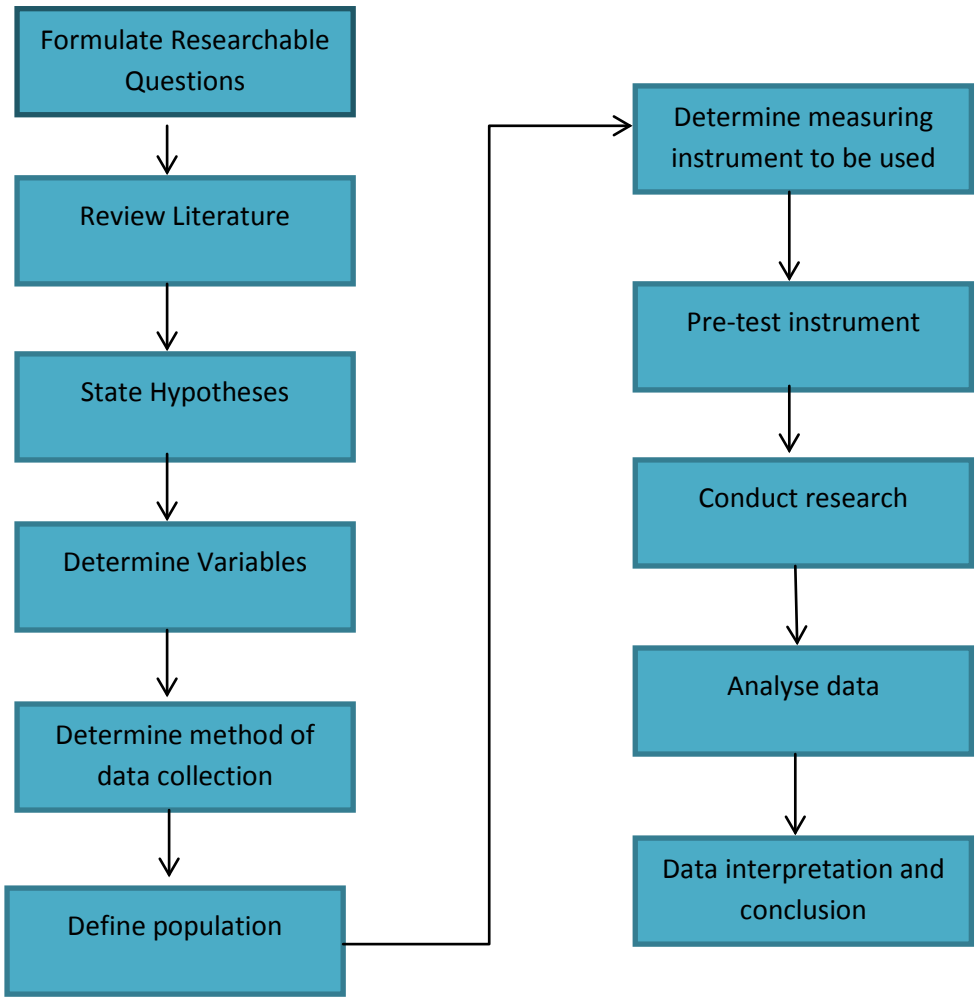
The questionnaires were printed and distributed by researcher to all departments included in the study. This occurred during the June 2013 period. The process leaders on each production line and per shift were tasked with handing out the questionnaires to employees. The researcher visited all departments and different shifts to ensure smooth circulation of questionnaires and at the same time answer any possible questions from employees.

3.2.5.6 Collection of questionnaires

The completed questionnaires were returned by team leader, process leaders and pharmacists to the researcher who recorded and compared responses per department against what was originally issued. Of the 506 questionnaires that were sent out, only 404 were returned. The plant manager and quality manager intervened to improve the response rate by requesting relevant line management to encourage employees to return the questionnaires, but there was no significant improvement. No incentives were used in the study to encourage response rates.

Figure 3.1 below illustrates the research methodology followed for this study.

Figure 3.1 Research process for the current study



3.3 RESPONSE RATE

According to Punch (2003), the percentage of people who respond to a survey is called the response rate; this rate is important and should not be left to chance. High survey response rates help to ensure that survey results are representative of the target population. A survey must have a good response rate in order to produce accurate and useful results. The response rate is obtained by dividing the number of people who submitted a completed survey by the number of people that the questionnaires were distributed to.

506 were distributed to all employees who were available at the time of the research. 404 questionnaires were received which resulted in a response rate of 79.84%.

According to Converse at el. (2008), there are now higher expectations for survey response rates. Response rates approximating 60% for most research should be the goal of researchers.

3.3.1 Geographic demarcations

Figure 3.2 indicates the gender balance of the respondents.

Figure 3.2 Response rate by gender

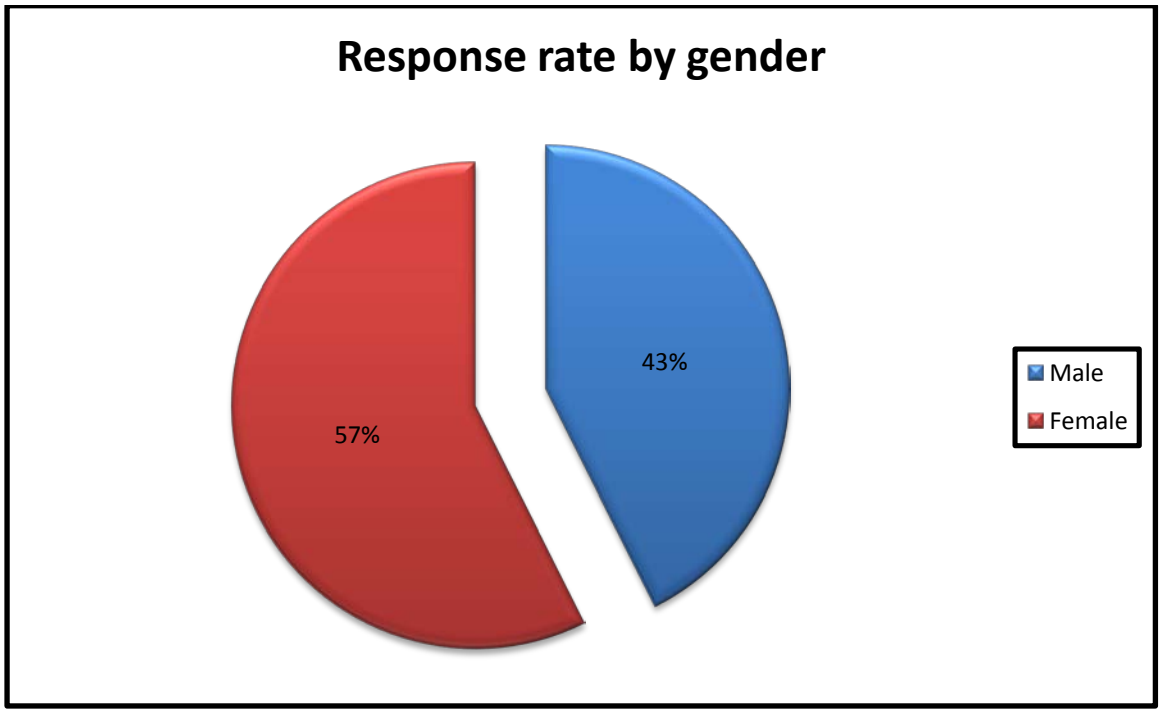


Figure 3.2 shows that 57% of respondents are female and 43% are male, which is a true representation of the facility as reflected in the HR database. Females are the majority of employees in most departments.

Figure 3.3 indicates that 42% of respondents are in the 30-39 and 40-49 age group, 11% are in the 20-29 years age group and only 5% is in the 50-59% age group. With the majority of the employees being below the 50-59 age group, the organisation can invest in the development of the employees as they still have many working years

before retirement. There is also an opportunity for knowledge transfer between the 50-59 age groups and the younger generation in the business.

Figure 3.3: Response rate by age group

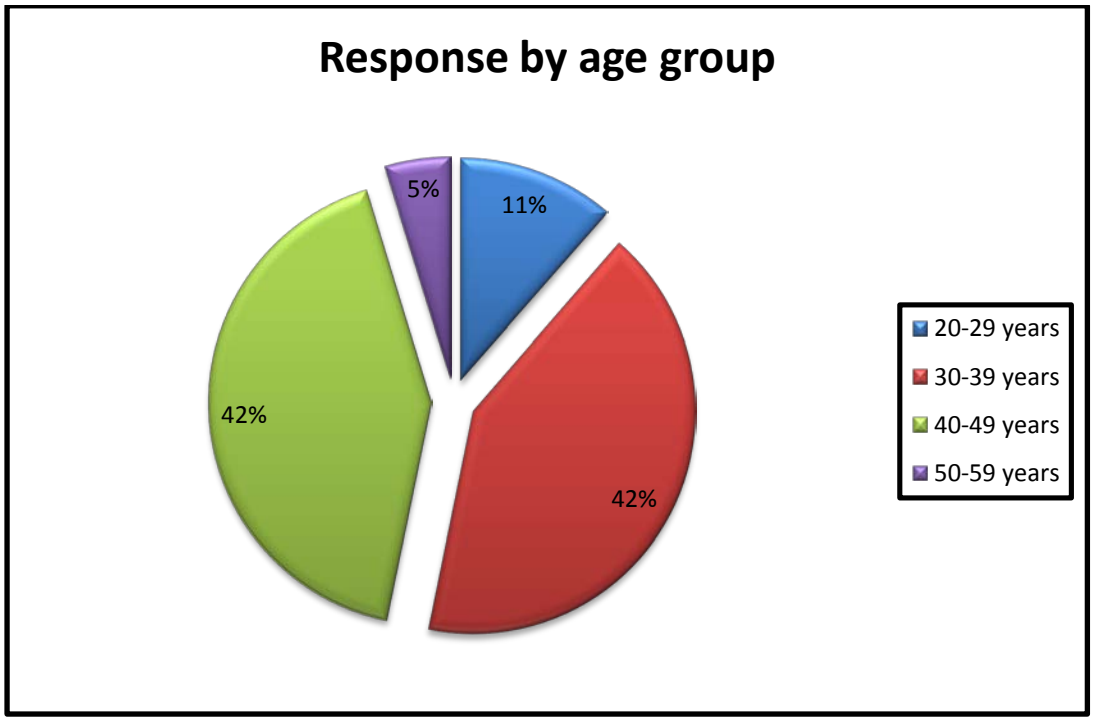


Table 3.3 below depicts the demographic representation of the sample

Table 3.3: Demographics composition of the sample: Gender and Age

Gender	Frequency	Percentage of respondents
Male	172	42.6
Female	232	57.4
Age	**Frequency**	**Percentage of respondents**
20-29 years	46	11.4
30-39 years	169	41.8
40-49 years	170	42.1
50-59 years	19	4.7

Figure 3.4 indicates 40 % of respondents use English as their home language, this is important as the preferred language of communication in the organisation is English and all company procedures and documentation is completed in English. 26 % of respondents speak isiXhosa and 33 % are Afrikaans, this reflects the cultural dynamic of Port Elizabeth and the Eastern Cape where the majority of people use isiXhosa or Afrikaans as their first language. Only 1 % of respondents use isiZulu as their home language.

Figure 3.4: Response rate by language

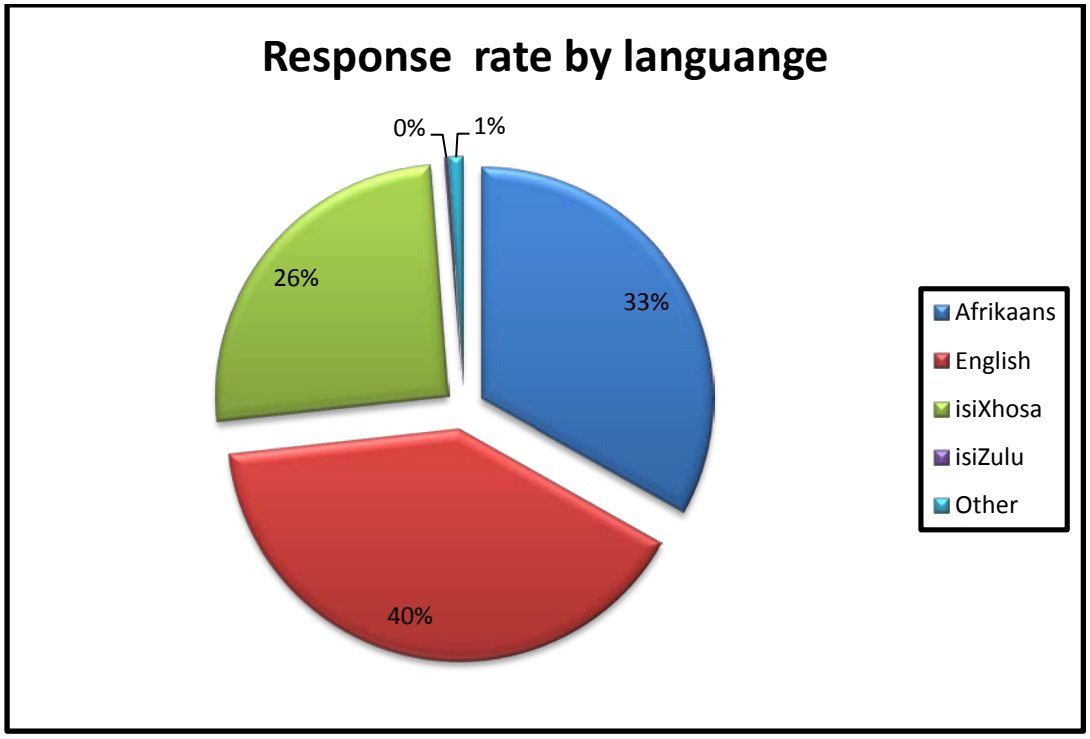


Table 3.4 below illustrates the composition of different home languages in the sample.

Table 3.4: Demographic composition of the sample: Language

Language	Frequency	Percentage
Afrikaans	134	33.2
English	162	40.1
isiXhosa	103	25.5
isiZulu	1	.2
Other	4	1.0

Figure 3.5 indicates that 5 % of the respondents have attained education level of grade 11 or lower; 45 % completed grade 12 or an education level equivalent to grade 12; 32 % of the respondents completed grade 12 and a diploma or certificate, while 5 % obtained a degree and another 5 % obtained a master's degree. The people with grade 11 and grade 12 education level are mostly in the production department hence the 50 % (which consist of 45% grade 12 or equivalent and 5% with grade 11 or lower) of respondents seen in below figure 3.6 consist of employees with a lower level of education, which is where the organisation needs to invest in human resource development. The company should encourage employees who were previously employed with grade 11, to enrol for a study programme that will assist them in completing grade 12 while they are still employed. The organisation has updated their recruitment policies and do not hire people with education levels below grade 12. Due to increased quality requirements by regulatory bodies, training has become a focus of auditors and this is an area that is not taken lightly by the South African Medicine Control Council.

Figure 3.5: Response rate by education level

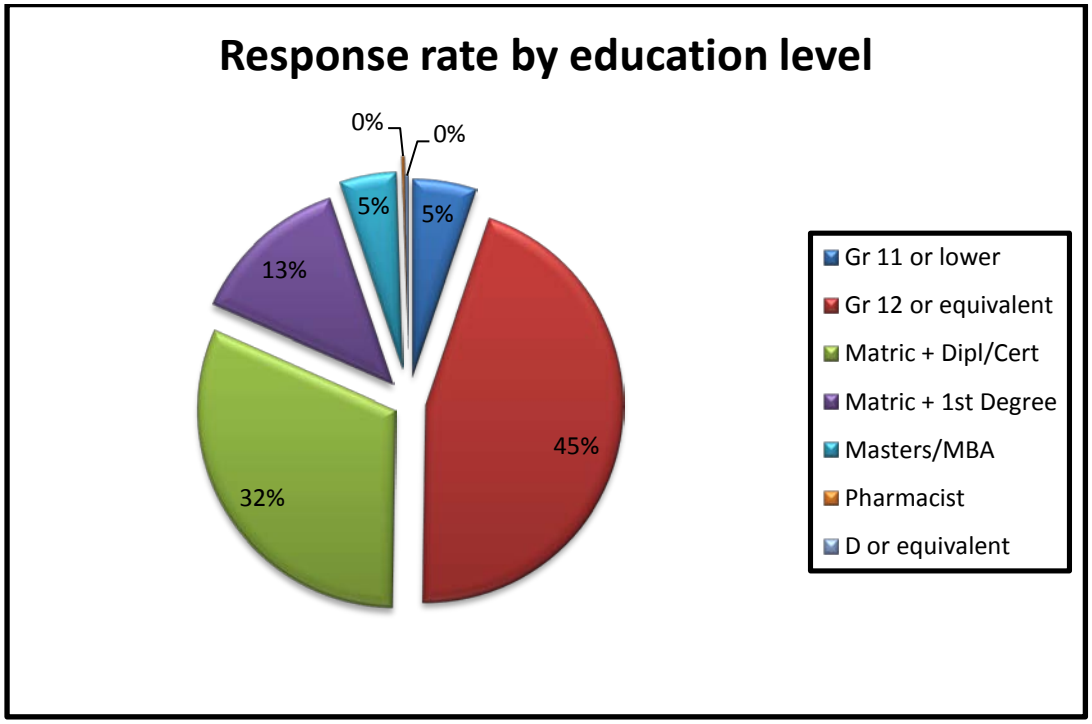


Figure 3.6 indicates that the majority of employees at FKMSA are in production (66.83%), quality (11.63%) and warehouse (9.90%). In total, they account for 88.37

% of the respondents in this study. The rest of the departments are considered as support or service departments

Figure 3.6: Response rate by department

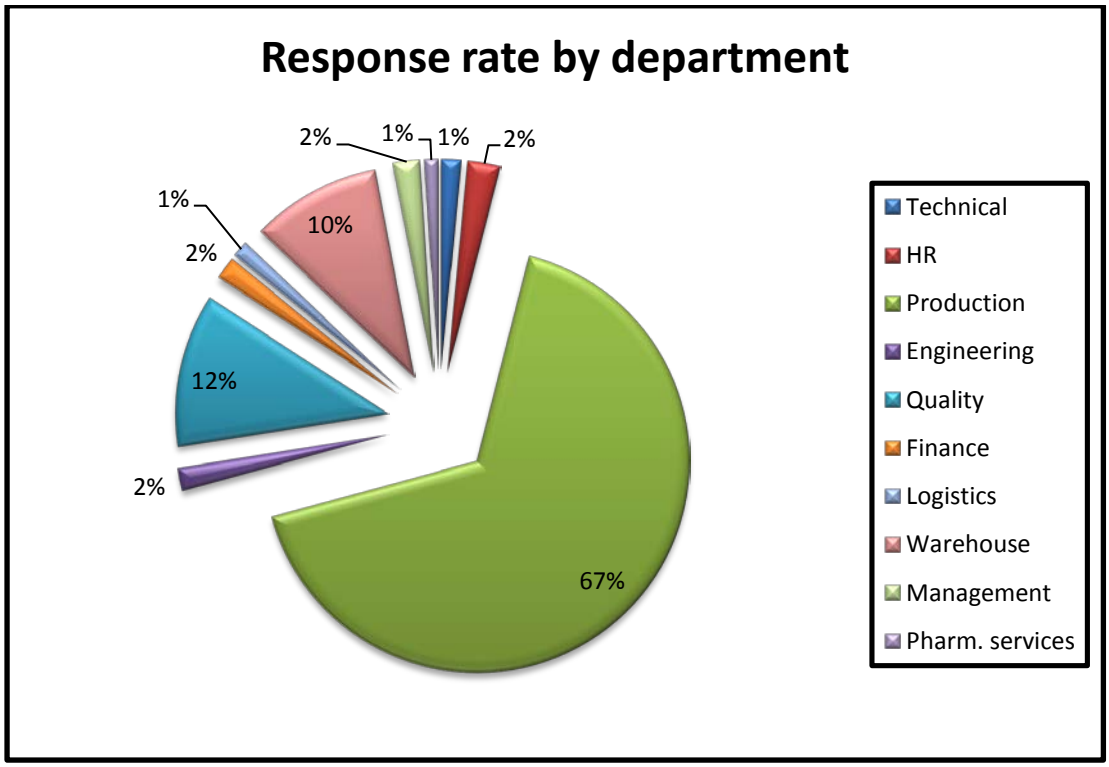


Table 3.5 Demographic composition of sample: Education and Department

Education	**Frequency**	**Percentage**
Gr 11 or lower	21	5.2
Gr 12 or equivalent	182	45.0
Matric + Diploma/Certificate	127	31.4
Matric + 1st Degree	53	13.1
Masters/MBA	19	4.7
Pharmacist	1	.2
Doctorate or equivalent	1	.2
Department	**Frequency**	**Percentage**
Technical	6	1.5
HR	10	2.5
Production	270	66.8

Engineering	7	1.7
Quality	47	11.6
Finance	7	1.7
Logistics	5	1.2
Warehouse	40	9.9
Management	8	2.0
Pharm. services	4	1.0

Figure 3.7 indicates that 38 % of respondents have 3-5 years' experience in their positions, 31 % have 6-10 years of experience, 21 % have 1-2 years of experience and 4 % has more than 11 years of experience. Only 6% of employees have less than 1 year of experience. The organisation has managed to retain the majority of employees in their position for a number of years, which is very important for the continuity and sustainability of the organisation.

Figure 3.7: Response rate by experience

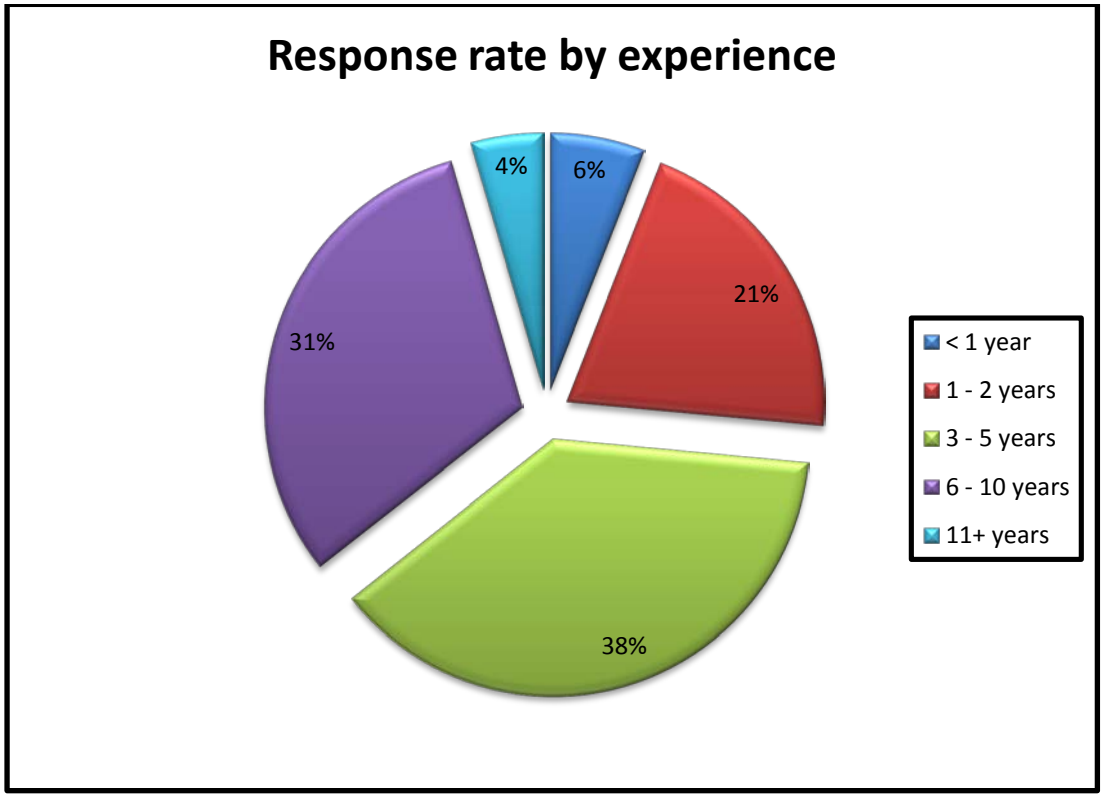


Table 3.6: Demographic composition of sample: Experience

Experience	Frequency	Percentage
< 1 year	24	5.9
1 - 2 years	83	20.5
3 - 5 years	153	37.9
6 - 10 years	126	31.2
11+ years	18	4.5

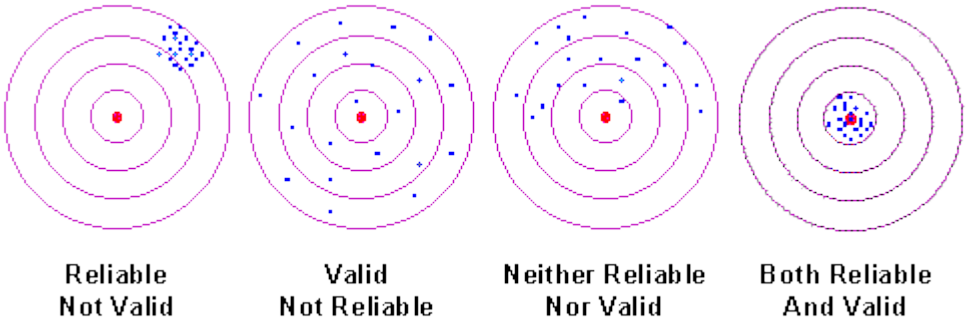
3.4 VALIDITY AND RELIABILITY

Reliability is the degree to which a measure is free from random error and therefore gives consistent results. It indicates internal consistency of the measurement device. It refers to the accuracy and precision of a measurement procedure and can be expressed in terms of stability, equivalence and internal consistency (Cooper & Schindler, 2003).

Validity is the extent to which a score truthfully represents a concept. Simply speaking, it is the accuracy of the measurement device and represents the ability of a scale to measure what it is intended to measure (Zikmund, 2000). Validity is expressed in two types: External and Internal (Saunders et al., 2009). External validity is about generalisation and internal validity ensures that a researcher's research design closely follows the principle of cause and effect.

To get a better understanding of the relationship between validity and reliability Fischer and Corcoran (2006) explained it using the below figure 3.8. Where the first circle represents that which is reliable but not valid, the second circle represent data that is valid but not reliable, the third circle is indicative of data that is neither reliable nor valid and the fourth circle is were data is both reliable and valid and it is the most acceptable data.

Figure 3.8: Validity and reliability illustration



Source: Fischer and Corcoran (2006)

According to Govender (2007), the research instrument must have validity to ensure it measures what it is supposed to measure. The pre-test study discussed in section 3.2.4.4 attempted to ensure the validity and reliability of questionnaire. As such, a pre-test of the questionnaire was also conducted with 10 quality assurance employees. These employees critically assessed the questionnaire in terms of face validity without recording any shortcomings. The restriction of the sample to only employees of FKMSA has also assisted with ensuring validity.

The Cronbach alpha was developed by Lee Cronbach in 1951 to provide a measure of the internal consistency of a test or scale; it is expressed as a number between 0 and 1. Internal consistency describes the extent to which all the items in a test measure the same concept or construct and hence it is connected to the inter-relatedness of the items within the test. Cronbach alpha is an important concept in the evaluation of assessments and questionnaires. It is mandatory that assessors and researchers estimate this quantity to add validity and accuracy to the interpretation of their data (Tavakol & Dennick, 2011).

Cronbach's alpha is the most common measure of internal consistency ("reliability"). It is most commonly used when the study has multiple Likert questions in a survey/questionnaire that form a scale and the researcher needs to determine if the scale is reliable.

A low value of alpha could be due to a low number of questions, poor interrelatedness between items or heterogeneous constructs. For example if a low

alpha is due to poor correlation between items then some should be revised or discarded. Items with low correlations are deleted. If alpha is too high it may suggest that some items are redundant as they are testing the same question but in a different context. A maximum alpha value of 0.90 has been recommended.

The below table is a guide for cronbach alpha value limits.

Table 3.7: Cronbach alpha value limits

Cronbach's alpha	Internal consistency
$\alpha = 0.9$	Excellent
$0.7 \leq \alpha < 0.9$	Good
$0.6 \leq \alpha < 0.7$	Acceptable
$0.5 \leq \alpha < 0.6$	Poor
$\alpha < 0.5$	Unacceptable

In this study the Cronbach coefficient alpha was used to calculate the internal consistency of the measuring instrument. Below, Table 3.8 depicts the Cronbach alpha values for the study and all the values are below 0.7 which are regarded as reliable outcomes.

Table 3.8: Cronbach alpha values of the measuring instrument

Measuring instrument	Alpha Value
Overall perception of quality	0.76
Awareness of quality	0.88
Management commitment	0.87
Rewards and recognition	0.73
Support for quality	0.85
Obstacles to quality improvements	0.86

3.5 ETHICAL CONSIDERATIONS

Ethical issues were recognised and addressed appropriately in this study. The researcher was present across the site in the various departments during the distribution of questionnaires and through observation and interaction with respondents, ensured that the research survey was conducted in an ethical and morally sensitive manner. The researcher was also available to clarify any concerns on the questionnaire. In addition, there was no force or pressure by managers on employees to submit the questionnaires.

The researcher ensured that anonymity, confidentiality, voluntary participation and that no potential harm or threat occurred to any respondent who participated in the research. A response to all respondents will be provided once the study is completed.

3.6 CONCLUSION

This chapter discussed the theoretical background of the research methodology of the study, it also explained the practical research approach used in this study. The following chapter analyses and interprets the data collected in the study.

CHAPTER 4 - PRESENTATION OF RESULTS

4.1 INTRODUCTION

The overall objective of the research undertaken in this study was to identify employee perceptions of quality at the FKMSA. The responses obtained from the respondents for each of the 21 questions is presented. Refer to Appendix A for the full questionnaire. The analysis has been conducted as outlined in Chapter three and is presented in a tabular and graphical format with explanations.

4.2 DATA ANALYSIS

The data should be accurate, complete and suitable for further analysis (Sekaran & Bougie, 2010). The researcher has to record and arrange the data and then apply various descriptive and inferential statistics or econometric concepts to explain the data and draw inferences (Saunders et al, 2009). A selection of an inappropriate statistical technique or econometrics model may lead to inaccurate interpretations. This may in turn result in failure to solve the research problem and answer research questions. According to Lind et al (2008), researchers can use a number of descriptive statistics concepts to explain data, such as frequency distributions or cumulative frequency distributions, frequency polygons, histograms, various types of charts like bar charts and pie charts, scatter diagrams, and box plots.

Researchers can make inferences and draw conclusions based on inferential statistics. Two main objectives in inferential statistics are to estimate a population parameter and to test hypotheses or claim about a population parameter (Triola, 2008). Researchers have to carefully select between varieties of inferential statistics techniques to test their hypotheses. For example, based on whether the researcher is using sample or census, there is the choice of using either t-tests or z-tests (Cooper & Schindler, 2006). In hypotheses testing, depending upon the number and nature of samples, a researcher has to decide between using either one sample t-test, or two sample (independent or dependent) t-tests, or doing ANOVA/MANOVA (Lind et al., 2008).

4.3 MULTIPLE REGRESSION ANALYSIS

The statistica version 10 (2010) computer software programme was utilised to test the relationship between quality perceptions of employees at FKMSA (independent variable) and overall perception, awareness of quality, rewards and recognition, management commitment, support for quality and obstacles to quality improvements.

4.3.1 The influence of overall quality in the organisation on quality perceptions.
The following hypotheses were formulated:
Hypothesis H1 stipulated that overall quality structures in the organisation exert a positive influence on quality employee perceptions.
H01. There is no significant relationship between quality perceptions and overall quality production.
According to the participants, overall quality does exert a major influence on the quality perceptions of the employees in the organisation. The hypothesis H1 is therefore supported, while the null hypothesis H01 is not supported. This means that improving the overall quality in the business will improve quality perceptions in the company.

4.3.2 The influence of awareness of quality systems on quality perceptions
The following hypotheses were formulated:
Hypothesis H2 stipulated that quality awareness exerts a positive influence on quality perceptions.
H02: There is no significant relationship between quality perceptions and awareness of quality systems.
The empirical results indicated that there is a significant positive influence between quality perceptions and awareness of quality systems (r 0.35, $p<0.05$). The hypothesis H2 is therefore supported while the null hypothesis H02 is not supported. This gives indicates that quality perceptions can be improved by increasing awareness of quality systems in the organisation.

4.3.3 The influence of management commitment on quality perception

The following hypotheses were formulated:

Hypothesis H3 stipulated that management commitment has a positive influence on quality perceptions.

H03: There is no significant relationship between quality perceptions and management commitment.

The empirical results show that there is a positive relationship between management commitment and quality perceptions ($r=0.42$, $p<0.05$). The hypothesis H3 is hence supported while the null hypothesis H03 is not. This means that by focusing on improving management commitment the organisation can increase quality perceptions of employees.

4.3.4 The influence of rewards and recognition on quality perceptions

The following hypotheses were formulated:

Hypothesis H4 stipulated that rewards and recognition exerts a positive influence on quality perceptions.

H04: There is no significant relationship between quality perceptions and rewards and recognition.

The empirical results indicate that rewards and recognition has an influence on quality perceptions($r=0.37$, $p<0.05$). The hypothesis H4 is hence supported while the null hypothesis H04 is not supported. This means that quality perception can be improved by focusing on improving the rewards and recognition system in the organisation.

4.3.5 The influence of support quality on quality perceptions.

The following hypotheses were formulated:

Hypothesis H5 stipulates that support for quality exerts a positive influence on quality perceptions.

H05: There is no significant relationship between quality perceptions and support for quality.

The empirical results indicate that support for quality has an influence on quality perceptions($r=0.35$, $p<0.05$). The hypothesis H5 is hence supported while the null

hypothesis H05 is not. This means that quality perception can be improved by the support for quality initiatives in the organisation.

4.3.6 The influence of obstacles to quality improvements on quality perceptions

The following hypotheses were formulated:

Hypothesis H6 stipulates that obstacles to quality improvements have a positive influence on quality perceptions.

H06: There is no significant relationship between quality perceptions and obstacles to quality improvements.

The empirical results indicate that obstacles to quality improvements has an influence on quality perceptions($r=0.36$, $p<0.05$). The hypothesis H6 is hence supported while the null hypothesis H06 is not supported. This means that quality perception can be improved by the support for quality initiatives in the organisation.

4.4 RESEARCH FINDINGS AND ANALYSIS

The findings and analysis are presented as frequency tables and graphically research objective and related questions (refer to Figures 4.1 to 4.6) and in tabular format (refer to Tables 4.3 and 4.8).

4.4.1 Analysis of questions per research objective

Table 4.1 lists the research questions that were used in this study and was obtained from Appendix A. These 21 questions address all the research objectives and sub-objectives for this study.

Table 4.1: Summary of research questions

No.	Nature of questions
1	Quality is the responsibility of all employees on the site
2	I have an understanding that I am producing a quality product or service
3	I am aware of the contents of the company quality policy
4	I understand the contents and requirements of the ISO9001 quality system with respect to my daily job
5	My manager/supervisor leads by example in adhering to the quality standards established in my workplace

6	My manager/supervisor ensures that quality is discussed regularly at meetings within my shift/department
7	I am paid to provide a good quality product or service
8	I am recognised for my suggestions to improve quality when these are implemented in my workplace
9	I believe that quality is more important to me than daily work schedules
10	I give as much time to quality as I do with safety and transformation issues
11	I have adequate work instructions and procedures to ensure I do my job correctly
12	I am given sufficient time to resolve quality problems
13	I am aware of the customer requirements for product quality
14	I am aware of the company quality performance policy and strive to improve it
15	I am aware of the quality objectives for my work area
16	I contribute towards a good quality product by ensuring that my equipment, methods and procedures are calibrated and updated
17	I believe that quality is the responsibility of the quality department
18	The quality system is simple and practical to adhere to
19	The company awards business to suppliers based on quality and not price
20	I believe quality is built into each design and process – it is not created by inspection
21	I am held accountable when my work is not 100% right first time

Table 4.2 is a summary the responses of all the six research objectives and the related questions. A total of 404 questionnaires were received from respondents and analysed. The below table gives a brief summary of the responses rates from strongly disagree to strongly agree.

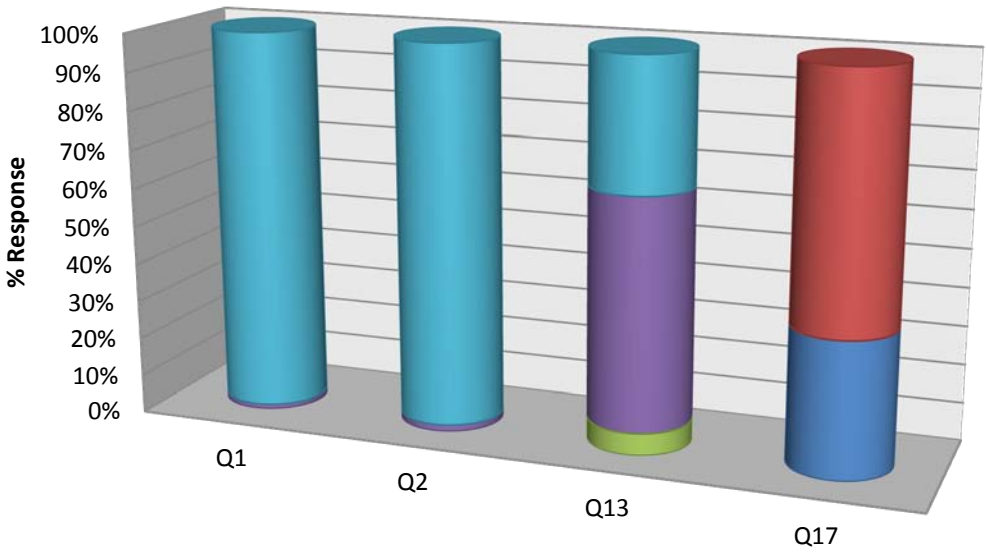
Table 4.2: Summary of responses per research objective and related questions

Summary of Research Objectives:	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Overall perception of quality	Q1				1.2%	98.8%	100%
	Q2				1.7%	98.3%	100%
	Q13			5.7%	60.1%	34.2%	100%
	Q17	35.1%	64.9%				100%
	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Awareness of quality	Q3	0.2%		4.7%	55.9%	39.1%	100%
	Q4		0.7%	18.1%	63.4%	17.8%	100%
	Q14		0.2%	5.0%	29.5%	65.3%	100%
	Q15		0.2%	1.2%	21.3%	77.2%	100%
	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Management commitment	Q5			18.6%	49.8%	31.7%	100%
	Q6		1.2%	31.9%	51.5%	15.3%	100%
	Q19		1.0%	5.7%	59.7%	33.7%	100%
	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Reward and recognition	Q7			2.2%	48.5%	49.3%	100%
	Q8	0.5%	0.2%	50.0%	41.8%	7.4%	100%
	Q21		0.2%	0.5%	40.8%	58.4%	100%
	Question numbers	Strognly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Support for quality	Q9		0.2%	0.5%	78.2%	21.0%	100%
	Q10		0.2%	7.2%	82.4%	10.1%	100%
	Q16			5.0%	23.5%	71.5%	100%
	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
Obstacles to quality improvement	Q11			7.2%	10.6%	82.2%	100%
	Q12	0.2%	55.0%	31.4%	12.9%	0.5%	100%
	Q18		20.0%	54.2%	25.7%		100%
	Q20	0.5%	0.7%	10.4%	56.7%	31.7%	100%

4.4.2 Overall perception of quality

Figure 4.1 is a graphical representation of the participant's response on overall perceptions of quality in the factory. The average mean for overall perception of quality is 3.975 which indicate a satisfactory level.

Figure 4.1 Overall perception of quality



	Q1	Q2	Q13	Q17
Strongly agree	98.8%	98.3%	34.2%	
Agree	1.2%	1.7%	60.1%	
Neither agree nor disagree			5.7%	
Disagree				64.9%
Strongly disagree				35.1%

Table 4.3: Descriptive statistics on overall perception of quality

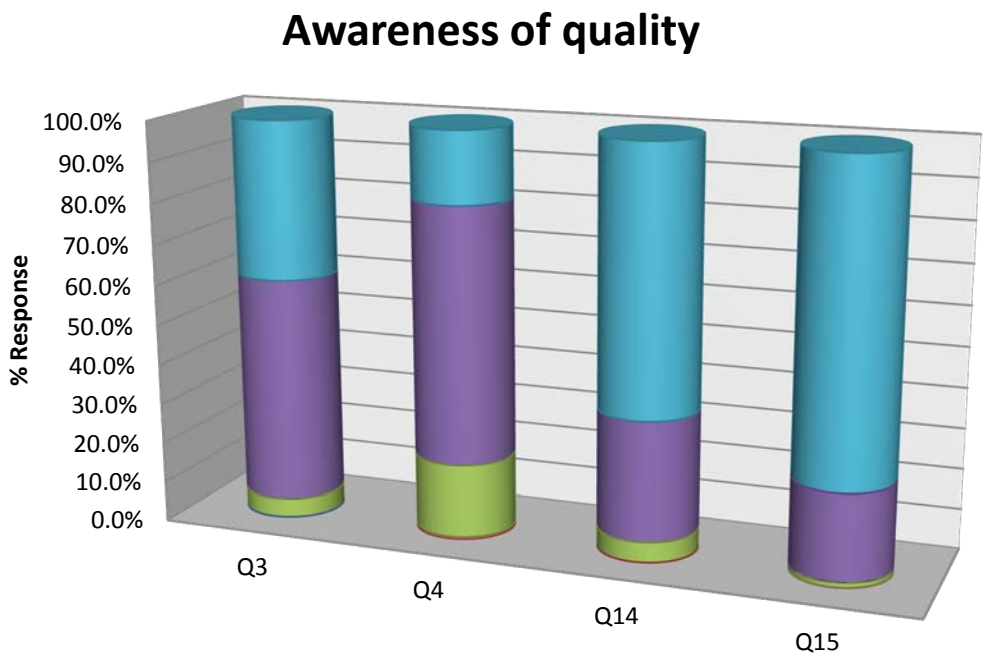
Summary of Research Objectives:	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
Overall perception of quality	**Q1**				1.2%	98.8%	100%	4.99	0.11
	Q2				1.7%	98.3%	100%	4.98	0.13
	Q13			5.7%	60.1%	34.2%	100%	4.28	0.56
	Q17	35.1%	64.9%				100%	1.65	0.48

Question 1,2,13 and 17 were aimed at measuring the overall perception of quality in the organisation. As can be seen above 95 % of respondents strongly agreed on Q1 and Q2, for Q13 60.1 % agreed and 34.2 % strongly agreed, for Q17 64.9 % disagreed and 35.1 % strongly disagreed. The responses to all the questions indicated that employees are aware of their responsibility in maintaining the overall quality in the organisation.

4.4.3 Awareness of quality

Figure 4.2 gives a graphical representation of the participant's responses on awareness of quality. The overall average mean for awareness of quality is 4.418 which indicates a satisfactory level.

Figure 4.2 Awareness of quality



	Q3	Q4	Q14	Q15
Strongly agree	39.1%	17.8%	65.3%	77.2%
Agree	55.9%	63.4%	29.5%	21.3%
Neither agree nor disagree	4.7%	18.1%	5.0%	1.2%
Disagree		0.7%	0.2%	0.2%
Strongly disagree	0.2%			

Table 4.4: Descriptive statistics on awareness of quality

	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
Awareness of quality	**Q3**	0.2%		4.7%	55.9%	39.1%	100%	4.34	0.59
	Q4		0.7%	18.1%	63.4%	17.8%	100%	3.98	0.62
	Q14		0.2%	5.0%	29.5%	65.3%	100%	4.60	0.60
	Q15		0.2%	1.2%	21.3%	77.2%	100%	4.75	0.47

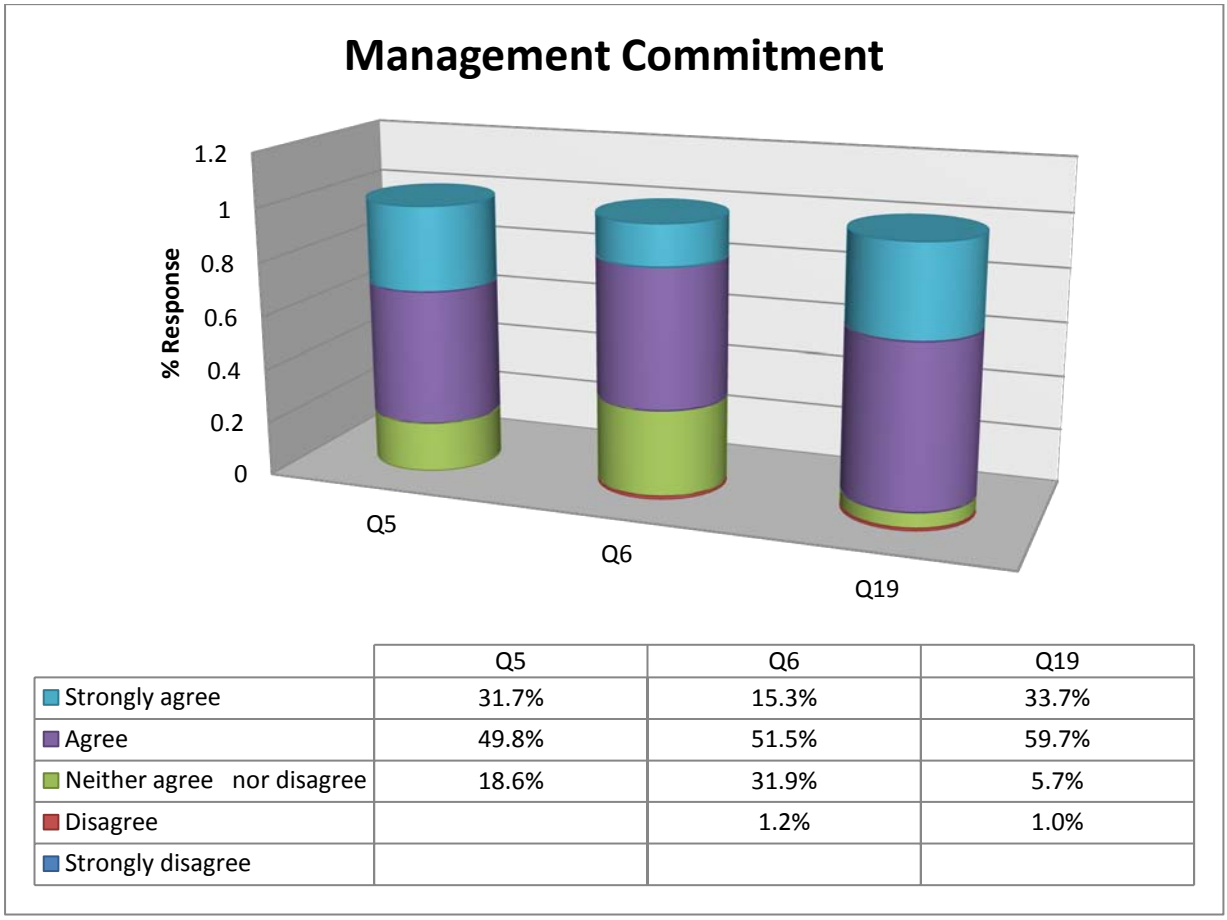
Questions 3, 4, 14 and 15 were aimed at answering sub-question two which is to ascertain employee perceptions in terms of awareness of the quality system and the organisation quality policy. For Q3, 55.9 % agreed and 39.1 % strongly agreed,

similar positive response is observed for Q4 where 63.4 % agreed and 17.8 % strongly agreed. For Q14, 29.5 % agreed and 65.3 % strongly agreed, similarly for Q15, 21.3 % agreed and 77.2 % strongly agreed. The responses to these questions indicate that the majority of employees are aware of the company's quality objectives and policies. A very small percentage of employees are not aware of quality systems overall objectives and the organisation can explore the possibility of a quality awareness programme throughout the factory.

4.4.4 Management commitment

Figure 4.3 is a graphical representation of participant's responses on management commitment. The overall average mean for management commitment is 4.067 which indicates a satisfactory level.

Figure 4.3 Management commitment



	Q5	Q6	Q19
Strongly agree	31.7%	15.3%	33.7%
Agree	49.8%	51.5%	59.7%
Neither agree nor disagree	18.6%	31.9%	5.7%
Disagree		1.2%	1.0%
Strongly disagree			

Table 4.5: Descriptive statistics on management commitment

Management commitment	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
	Q5			18.6%	49.8%	31.7%	100%	4.13	0.70
	Q6		1.2%	31.9%	51.5%	15.3%	100%	3.81	0.70
	Q19		1.0%	5.7%	59.7%	33.7%	100%	4.26	0.61

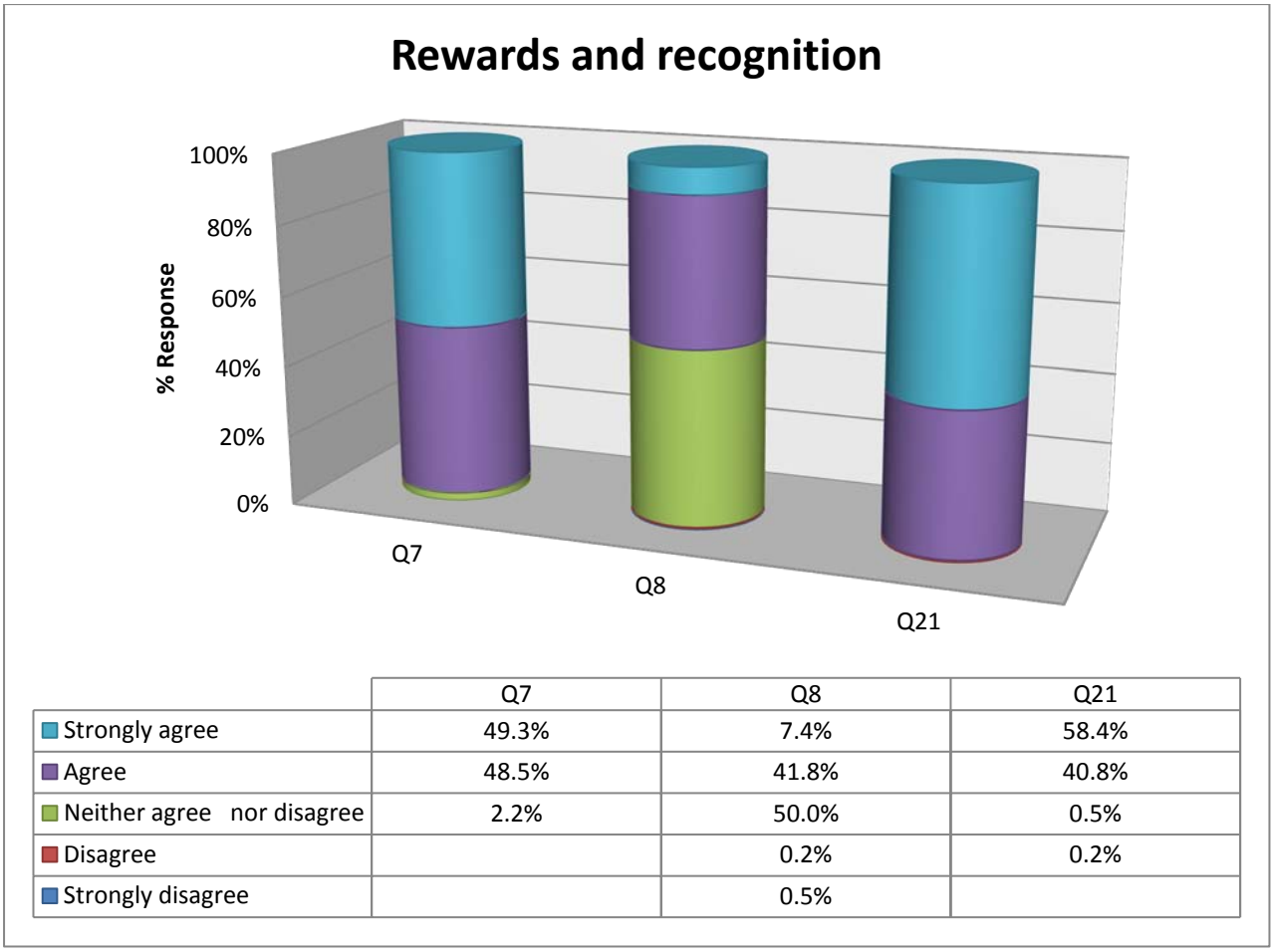
For question 5, 6 and 19, the average mean score is 4.067 in relation to management commitment. This indicates that to some extend employees at FKMSA view management commitment to quality as an integral part of the QMS. For Q5, 49.8 % agreed and 31.7 % strongly agreed that their managers lead by example in adhering to quality standards in the organisation. This indicates that managers and supervisors apply the company quality standards.

For Q6, 51.5 % agreed and 15.3 % strongly agreed that quality issues are discussed during departmental meeting. This shows that quality issues, such as deviations, CAPA and change controls are made visible and given the necessary attention by departmental managers. For Q 19, 59.7 % agree and 33.7 % strongly agree that management only source material from quality approved suppliers and business is only awarded based on quality.

4.4.5 Reward and recognition

The response for rewards and recognition yielded an average mean of 4.196 which indicates a positive rate as the mean is above 3.

Figure 4.4: rewards and recognitions



	Q7	Q8	Q21
Strongly agree	49.3%	7.4%	58.4%
Agree	48.5%	41.8%	40.8%
Neither agree nor disagree	2.2%	50.0%	0.5%
Disagree		0.2%	0.2%
Strongly disagree		0.5%	

Table 4.6: Descriptive statistics on rewards and recognition

Reward and recognition	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
	Q7			2.2%	48.5%	49.3%	100%	4.47	0.54
	Q8	0.5%	0.2%	50.0%	41.8%	7.4%	100%	3.55	0.66
	Q21		0.2%	0.5%	40.8%	58.4%	100%	4.57	0.52

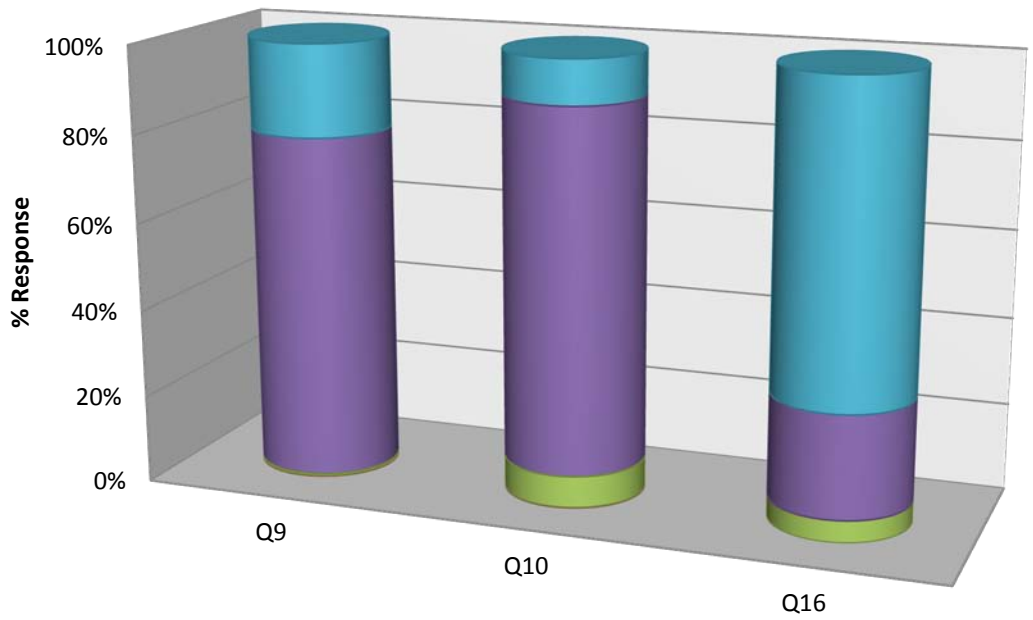
Questions 7, 8 and 21 were aimed at measuring the relationship between rewards and recognition and the employee's perception of quality. For Q7 48.5 % agreed and 49.3 % strongly agreed which indicated that the majority of employees believe that they are paid or rewarded for making a good quality product. For Q21, 40.8 % agreed and 58.4 strongly agreed indicating that overall, employees are held accountable and take ownership for making a quality product.

A concern is the response observed in Q8 where 50 % neither agreed nor disagree with being recognised for suggestions made to improve quality in their work place. This can indicate that the organisation needs to place focus on rewards and recognition programmes in the business.

4.4.6 Support for quality

The response for rate for support for quality yielded an average mean of 4.29, which indicates that most employees support quality initiatives and see quality as part of their daily functions.

Figure 4.5: Support for quality



	Q9	Q10	Q16
Strongly agree	21.0%	10.1%	71.5%
Agree	78.2%	82.4%	23.5%
Neither agree nor disagree	0.5%	7.2%	5.0%
Disagree	0.2%	0.2%	
Strongly disagree			

Table 4.7: Descriptive statistics on support for quality

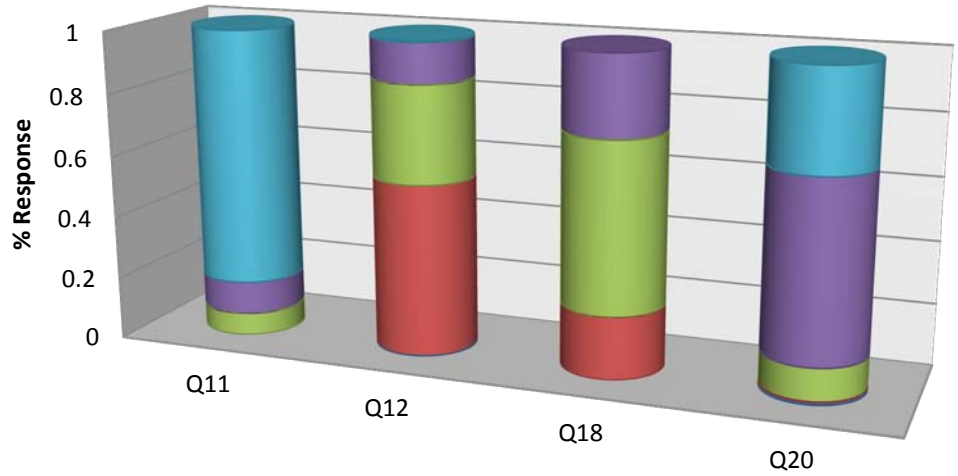
Support for quality	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
	Q9		0.2%	0.5%	78.2%	21.0%	100%	4.20	0.43
	Q10		0.2%	7.2%	82.4%	10.1%	100%	4.02	0.43
	Q16			5.0%	23.5%	71.5%	100%	4.67	0.57

Question 9, 10 and 16 measure the employees' support for quality at FKMSA. For Q9 78.2 % agreed and 21.0 % strongly agreed, showing that they believe that quality is more important than their daily activities. For Q10 82 % agreed and 10.1 % strongly agreed that enough attention and time was given to quality issues on a daily basis. For Q16 23.5 % agreed and 71.5 % strongly agreed, showing that employees ensure that their equipment, methods and procedures comply with the required quality standards.

4.4.7 Obstacles to quality improvement

An average mean of 3.642 was obtained for responses relating to obstacles to quality improvements. This indicates an overall satisfactory level.

Figure 4.6 Obstacles to quality improvement



	Q11	Q12	Q18	Q20
Strongly agree	82.2%	0.5%		31.7%
Agree	10.6%	12.9%	25.7%	56.7%
Neither agree nor disagree	7.2%	31.4%	54.2%	10.4%
Disagree		55.0%	20.0%	0.7%
Strongly disagree		0.2%		0.5%

Table 4.8: Descriptive statistics on obstacles to quality improvement

Obstacles to quality improvement	Question numbers	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Mean	SD
	Q11			7.2%	10.6%	82.2%	100%	4.75	0.58
	Q12	0.2%	55.0%	31.4%	12.9%	0.5%	100%	2.58	0.73
	Q18		20.0%	54.2%	25.7%		100%	3.06	0.68
	Q20	0.5%	0.7%	10.4%	56.7%	31.7%	100%	4.18	0.68

Questions 11, 12, 18 and 20 measured the level of barriers to quality improvement initiatives. For Q11, 82.2 % strongly agreed that they are provided with adequate work instructions to enable them to carry out their functions in line with required quality standards. For Q20, 56.7 % agree while 31.7 % strongly agreed, indicating

that the majority of employees believe that quality is built into each design and process step.

Responses observed on Q12 and Q18 are a concern as they revealed that the majority of employees see the QMS as a tool that is not easy to adhere to. They also believe that not enough time is provided to resolve quality issue and hence this can limit the opportunity to improve quality systems and processes.

4.5 CONCLUSION

Chapter four reported the descriptive statistics of the research by analysing and providing a detailed interpretation of the results. Based on the results observed in this study, the employees have an overall satisfactory perception of quality in the organisation and are aware of the importance of maintaining high quality standards in the organisation. The results also indicated the areas that need improvement in upholding the quality objectives of the company.

The following chapter provides an overall summary of the research and also suggests recommendations that can be applied by the business.

CHAPTER 5 - CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

In this chapter the researcher discusses the overview of the study and draws conclusions gleaned from the findings. Recommendations and potential improvement areas for the organisations are then outlined. Finally, areas of further study are suggested.

5.2 OVERVIEW OF THE STUDY

In Chapter one, the study introduced the pharmaceutical industry and the importance of quality perceptions of employees in the maintenance of the QMS. The author also discussed FKMSA and the role of quality assurance to this facility. The importance and relevance of the study was outlined followed by a brief discussion on the primary and secondary research objectives of the study. The limitations of the study were highlighted and the chapter was concluded with a brief outline of the entire study.

In Chapter two, literature related to both the primary and secondary objectives was collected from different sources and reviewed in line with the research question. Quality assurance was defined in-line with the pharmaceutical industry; this was then followed by a details review of the different aspects of the QMS. The researcher also reviewed literature based on employee perceptions, rewards and recognitions, management commitment to quality, support for quality and barriers to quality improvements. In each section the gathered information was interpreted.

In Chapter three, the methodology of this study was outlined and discussed. The research followed a quantitative methodology. Information was gathered from the selected target group using a questionnaire which was distributed and collected in June 2013. 404 questionnaires were received which resulted in a response rate of 79.84%.

In Chapter four, data analysis was conducted using STATISTICA Version 11 (2011). Data interpretation was conducted for each research objective and a summary provided for each objective. The reliability and variability of the study was done using multiple regression analysis.

5.2.1 Overall perceptions of quality

The overall employee perception of quality in the organisation was measured by asking the following questions:

- Quality is the responsibility of all employees on the site;
- I have an understanding that I am producing a quality product or service;
- I am aware of the customer requirements for product quality; and
- I believe that quality is the responsibility of the quality department.

From the response percentage on the above questions it was concluded that employees take personal ownership for quality in their respective work areas.

Employee perception is a critical factor that can results in a significant difference in the quality of the products manufactured by the organisation. Pareek (2001) agrees that this can result in employees having a positive relationship with the company and putting in more effort in making a quality product, hence there is a good chance the employee will be productive and will place more focus on organisational goals of producing high quality products.

Organisational leadership needs to become aware of the power of perception, learn what circumstances are likely to cause incorrect perceptions, learn how to manage employee perceptions to the fullest extent possible and always approach perception as the perceiver's reality (McConnell,1994).

Quality in the pharmaceutical industry is one of the most important aspects of the day to day business functions and any compromise in quality can potentially lead to fatality. It is important for FKMSA to use the correct communication channels for quality related issues and to ensure that employees are able to interpret the communication accurately and positively.

5.2.2 Awareness of quality

To assess the awareness of quality in the organisation the following questions were asked to participating employees.

- I am aware of the contents of the company quality policy;
- I understand the contents and requirements of the ISO9001 quality system with respect to my daily job; and
- I am aware of the company quality performance and strive to improve it.

The responses indicated that the majority of employees are aware of the company quality objectives and policies. A very small percentage of employees are not aware of quality systems overall objectives which means that the organisation should explore the possibility of quality awareness programmes throughout the factory.

5.2.3 Management commitment

In Chapter two Babakus et al. (2003) explain management commitment as the direct involvement by the highest level of leadership in a specific and critical section of an organisation. In quality, management commitment includes implementing and being members of the quality committee, formulating and establishing quality policies and objectives, allocating resources and training, overseeing implementation at all levels of the organisation and the evaluating and monitoring of the outcomes.

Ashill, Carruthers and Krisjanous (2006) go further to say that management cannot just direct the company, but they must ensure that the quality decisions and actions are taken and implemented. Management's role in quality management has also been highlighted as one of the crucial requirement for a successful quality improvement implementation.

The average mean score of the findings in relation to management commitment is 4.067. This indicates that to some extent employees at FKMSA view management commitment to quality as an integral part of the QMS.

To encourage a culture of quality first management at FKMSA, management must take hands on approach on quality issues and include a quality management review in their periodic review of business performance. Management must show urgency on quality related issues to be able get the buy-in from employees at all levels.

5.2.4 Rewards and recognitions

According to Beer et al (1984), organisations must reward employees because, in return, they are more likely to get competent individuals who work with a high level of performance and loyalty. Individual employees, in exchange for their commitment, expect certain extrinsic rewards in the form of promotions, salary, fringe benefits, bonuses, or stock options. Individuals also seek intrinsic rewards, such as feelings of competence, achievement, responsibility, significance, influence, personal growth and contributing meaningfully. Employees judge the adequacy of their exchange with the organisation by assessing both sets of rewards.

The main purpose of the organisations rewards and recognition programmes is to keep employees motivated and productive. These programmes can be used as effective methods of reinforcing company expectations and goals including the organisation quality objectives.

5.2.5 Support for quality

To assess the support for quality systems in the organisation the following questions were asked.

- I believe that quality is more important to me than daily work schedules;
- I give as much time to quality as I do with safety and transformation issues; and

- I contribute towards a good quality product by ensuring that my equipment, methods and procedures are calibrated and updated.

From the participant's response it could be concluded that employees are supportive of the quality systems and involve quality in their daily activities.

5.2.6 Obstacles to quality improvements

Beckford (2002) identifies four areas that can lead to barriers in the achievement of quality in the organisation. These areas include systems and procedures, culture, organisation design and management perspectives of quality.

One of the strategies that can be applied to overcome the limitation to quality is by recognising that mistakes are opportunities for learning, the opportunity to align a process, system, skill or behaviour to prevent re-occurrences. However, in most organisations and in many circumstances, the cause of the error can be traced to some failure in the design or execution of a process, in the training of employee or in the equipment provided for the completion of the task. These aspects should be the first focus of attention and in a quality organisation, will inhibit the use of disciplinary action.

For the organisation to create the correct attitude toward the development of quality, it must always be considered and recognised as an issue. When product related investigations are undertaken quality issues must be considered at the onset of the investigation. It is essential that quality be treated as a potential part of the problem and be considered as a possible cause of the problem. Even if the organisation is performing well, a positive attitude to quality needs to be developed and maintained.

Responses observed on Q12 and Q18 are a concern as the majority of employees see the QMS as a tool that is not easy to adhere to. They also believe that not enough time is provided to resolve quality issue and hence this can limit the opportunity to improve quality systems and processes.

5.3 SUMMARY

In line with the literature review in this study, it can be concluded that awareness of quality, reward and recognition, support of quality, management commitment and obstacles to quality in the organisation are vital to producing a high quality product and has an impact on the employee perceptions of quality in the organisation.

It can also be concluded that the majority of employees are aware of their personal responsibilities in ensuring that quality is maintained in every step of the manufacturing process. Employees are also familiar with the quality objectives of the organisation.

Further study in the current QMS and would benefit for the company.

The organisation should continue investing in training and awareness programmes and frequently update employees on the quality requirements of the pharmaceutical industry. They also need implement a rewards and recognition programme which should be visible and accessible to employees at all levels of the organisation.

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Dear Respondent

I am currently studying towards my Master's degree in Business Administration. For the purposes of my study, I intend to carry out research on employee perception of quality at FKMSA. The investigation does require the completion of a questionnaire by employees. Kindly note that by responding to the questionnaire, you would not only be making a valuable contribution to this research, but also provide valuable information that has a bearing on the success and effectiveness of the quality management system in the company.

It would therefore be appreciated if you would complete the attached questionnaire. Your individual responses are very important for the success of this research so therefore please do not consult with your other team members. The answering of questions in this questionnaire should not take more than 10 minutes.

You are assured on the confidentiality of your responses, as it would be done anonymously, in that your name is not required on the questionnaire. Your participation is voluntary and you may withdraw at any time without giving any reasons.

Kindly return your completed questionnaire to your direct supervisor by no later than 30 Jun 2013.

Thank you for your co-operation and the time that you have set aside for this research.

Yours faithfully

Nomasango Ida Bango

Research Supervisor: Bux Heather

SECTION A – BACKGROUND INFORMATION

This section of the questionnaire refers to background or biographical information. Although we are aware of the sensitivity of the questions in this section, the information will allow us to compare groups of respondents. Once again, we assure you that your response will remain anonymous.

Your cooperation is appreciated.

PLEASE ANSWER THE FOLLOWING QUESTIONS BY CROSSING (×) IN THE RELEVANT BLOCK

1. Gender

Male	1
Female	2

2. Age

20-29 years	1
30-39 years	2
40-49 years	3
50-59 years	4
60 plus	5

3. Home language

Afrikaans	1
English	2
isiXhosa	3
isiZulu	4
Specify other	5

4. Educational/ professional qualification

Grade 11, equivalent or lower	1
Grade 12 or equivalent	2
Matric plus diploma or certificate	3
Matric plus 1st degree	4
Master's degree or MBA	5
Pharmacist	6
Doctoral Degree or equivalent	7

5. **The department in which you are employed within the organisation**

Technical	1
Human Resources	2
Production	3
Engineering	4
Quality	5
Finance	6
Logistics	7
Warehouse	8
Management	9
Pharmaceutical services	10

6. **Years of experience in your role or function**

Less than 1 year	1
1-2 years	2
3-5 years	3
6-10 years	4
More than 10 years	5

7. **Your job grade**

Operator	1
Team Leader	2
Process Leader	3
Administrator	4
Pharmacist	5
Manager	6
Supervisor	7
Microbiologist	8
Analyst	9
Technician	10

SECTION B

PLEASE ANSWER THE FOLLOWING QUESTIONS BY CROSSING (×) IN THE RELEVANT BLOCK

1. Strongly disagree
2. Disagree
3. Neither agree nor disagree
4. Agree
5. Strongly agree

QUESTIONS	**1**	**2**	**3**	**4**	**5**
Quality is the responsibility of all employees on the site					
I have an understanding that I am producing a quality product or service					
I am aware of the contents of the company quality policy					
I understand the contents and requirements of the ISO9001 quality system with respect to my daily job					
My manager/supervisor leads by example in adhering to the quality standards established in my workplace					
My manager/supervisor ensures that quality is discussed regularly at meetings within my shift/department					
I am paid to provide a good quality product or service					
I am recognised for my suggestions to improve quality when these are implemented in my workplace					
I believe that quality is more important to me than daily work schedules					
I give as much time to quality as I do with safety and transformation issues					
I have adequate work instructions and procedures to ensure I do my job correctly					
I am given sufficient time to resolve quality problems					
I am aware of the customer requirements for product quality					
I am aware of the company quality performance					

and strive to improve it					
I am aware of the quality objectives for my work area					
I contribute towards a good quality product by ensuring that my equipment, methods and procedures are calibrated and updated					
I believe that quality is the responsibility of the quality department					
The quality system is simple and practical to adhere to					
The company awards business to suppliers based on quality and not price					
I believe quality is built into each design and process – it is not created by inspection					
I am held accountable when my work is not 100% right first time					