An Implementation Framework for Statistical Process Control in Small to Medium-sized Enterprises: A South African Context

by

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Declaration

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Date: December 2019

Abstract

A fundamental trait of our everyday environment is that no subsequent event is precisely repeatable. Despite the best effort of manufacturing entities, the probability is low that two consecutive batches of material will have exactly the same characteristics. Variation is inherent to system-based processes as a combination of people, materials, methods, machines and the environment, can contribute to a natural randomness in processes.

The implementation of Statistical Process Control (SPC) is driven by the desire to be more proactive as the reactiveness of an inspection-based quality control system is unreliable, costly and time-consuming. SPC is commonly overlooked due to a lack of awareness of the potential benefits and it commonly fails due to an unclear objective and ill-constructed implementation plan. This study is an intervention which surveys existing SPC implementation publications. The study identifies strengths and weaknesses of existing published literature, highlighting key areas of SPC implementation. The study further focuses on the organisational and methodological critical success factors (CSFs), which would be relevant to South African small to medium-sized enterprises (SMEs), utilising the identified CSFs and deficiencies to develop a framework for the sustainable and effective implementation of SPC in manufacturing SMEs.

The research methodology consists of three phases, which are the literature review, framework development and the validation of the framework as a case study using participatory action research. The literature survey was performed as a random literature survey coupled with a systematic literature review of SPC implementation frameworks. The research branches into implementation strategies and methodologies used for other continuous improvement initiatives.

According to the reviewed frameworks the most commonly identified gaps are a lack of focus on: (1) measurement system capability; (2) process prioritisation; (3) identification of critical to quality characteristics; (4) training and education; (5) validation of the framework; (6) step-by-step procedure with a logical flow and (7) problem-solving. A total of 81% of the articles mentioned training and education as a critical success factor, and 69% of the same reviewed articles also mentioned management commitment as a critical success factor, in contrast to the 13% which mentioned statistical thinking.

This study contributes to the domain of quality management and continuous improvement by addressing a tangible issue in a specific manufacturing organisation in which a previous attempt on implementing SPC failed. The study addresses the lack of substance, which current literature offers regarding strategic approaches on the implementation of SPC in smaller organisations with limited resources.

Opsomming

'n Kern eienskap van ons alledaagse omgewing is dat geen opeenvolgende gebeurtenis, presies herhaalbaar is nie. Ten spyte van vervaardigingsentiteite se beste poging, is die waarskynlikheid laag dat twee opeenvolgende produkte presies dieselfde eienskappe sal hê. Variasie is eie aan stelselgebaseerde prosesse omdat 'n kombinasie van mense, materiale, metodes, masjiene en die omgewing moontlik kan bydra tot ‘n natuurlike variasie.

Die implementering van Statistiese Prosesbeheer word aangedryf deur die begeerte om meer proaktief te wees aangesien die reaktiwiteit van 'n inspeksiegebaseerde kwaliteitsbeheerstelsel onbetroubaar, duur en tydrowend is. Statistiese Prosesbeheer word oor die hoof gesien weens 'n gebrek aan die bewustheid van potensiële voordele, en dit misluk as gevolg van 'n onduidelike en swak implementeringsplan. Hierdie studie evaluaeer bestaande publikasies rakend die implementering van statistiese prosesbeheer. Die studie beoog om sterk punte en swakpunte van bestaande gepubliseerde literatuur te identifiseer en om kern aspekte rakend die implementering van statistiese prosesbeheer uit te lig. Die studie fokus verder op organisatoriese en metodologiese kritiese suksesfaktore, wat van toepassing kan wees op Suid Afrikaanse klein tot medium-grootte ondernemings (KMOs), en gebruik die geïdentifiseerde kern aspekte en swakpunte om 'n raamwerk te ontwikkel vir die volhoubare en doeltreffende implementering van statistiese prosebeheer vir KMOs.

Die navorsingsmetodologie bestaan uit drie fases, naamlik die literatuuroorsig, raamwerkontwikkeling en die evaluaering van die raamwerk as 'n gevallestudie deur gebruik te maak van aksienavorsing. Die literatuuropname is uitgevoer as 'n ongestruktureerde literatuuroorsig, tesame met 'n sistematiese literatuurooorsig van implementeringsraamwerke. Die navorsing behandel ook implementeringstrategieë en metodologieë van ander deurlopende verbeteringsinisiatiewe.

Volgens die hersiene raamwerke is die algemeenste geïdentifiseerde tekortkoming 'n gebrek aan fokus op: (1) metingstelselvermoë; (2) prioritisering van prosesse; (3) identifisering van kritiese kwaliteitskenmerke; (4) opleiding; (5) validering van die raamwerk; (6) n’ stap-vir-stap prosedure met 'n logiese vloei en (7) probleemoplossing. Altesaam 81% van die artikels noem opleiding as 'n kritiese suksesfaktor, waar 69% van die artikels bestuurstoewyding genoem het, in teenstelling met die 13% wat statistiese denkwyse noem.

Hierdie studie dra by tot die gebied van kwaliteitsbestuur en deurlopende verbetering deur 'n werklike probleem in 'n spesifieke vervaardigingsorganisasie aan te spreek, weens n mislukking met vorige pogings. Die studie behandel die gebrek aan inhoud wat deur bestaande literatuur verskaf word, rakend strategiese benaderings tot die implementering van die statisties proses beheer in KMOs met beperkte hulpbronne.

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Table of Contents

List of Figures

List of Tables

List of Equations

Glossary

Acronyms and Abbreviation

AIAG	-	Automotive Industry Action Group
COPQ	-	Cost of Poor Quality
COQ	-	Cost of Quality
CSF	-	Critical Success Factors
CTQ	-	Critical to Quality
CUSUM	-	Cumulative Sum
DOE	-	Design of Experiments
DPMO	-	Defects per Million Opportunities
EWMA	-	Exponentially Weighted Moving Average
FMEA	-	Failure Modes and Effects Analysis
FMECA	-	Failure Modes, Effects and Criticality Analysis
FTR	-	First Time Right
GRR	-	Gauge Repeatability and Reproducibility
I-MR	-	Individual Moving Range
ISO	-	International Organisation of Standardization
LCL	-	Lower Control Limit
LSL	-	Lower Specification Limit
MSA	-	Measurement System Analysis
NIR	-	Near-Infrared Spectroscopy
OCAP	-	Out of Control Action Plan
PCI	-	Process Capability Index
QCD	-	Quality, Cost and Delivery
QMS	-	Quality Management System
RPN	-	Risk Priority Number
SME	-	Small to Medium-sized Enterprises
SPC	-	Statistical Process Control
TPS	-	Toyota Production System
UCL	-	Upper Control Limit
USL	-	Upper Specification Limit

Nomenclature

Symbol	Description	Units
$\overline{X}$	X Bar	n/a
R	Range	n/a
$\bar{R}$	R Bar	n/a
MR	Moving Range	n/a
$\overline{MR}$	Moving Range Bar	n/a
σ	Sigma/Standard Deviation	n/a

Chapter 1 – Introduction and problem statement

Quality is the degree to which a set of inherent characteristics or requirements, generally defined by the client or customer, is adhered to (ISO, 2015). It is based on absolute customer satisfaction and in a manufacturing environment, is driven by conformance to requirements and short lead times at a competitive price for the client (Weckenmann, Akkasoglu & Werner, 2015). Profit-driven manufacturing entities aspire to possess these abilities by striving tirelessly towards manufacturing excellence. Turney (1989) defines manufacturing excellence as the deliberate and continuous improvement of the entire business process with the aspiration to obtain a competitive edge in the market. A competitive edge driven by continuous improvement highlights a company's intent towards:

- Waste reduction (time, material, downtime, etc.)
- An improved quality rate
- Reduced lead times (changeover and delivery from supplier and to client) and
- Employee development

The quality rate can be improved by consistently manufacturing compliant products (Gejdoš, 2015). The aim is to continuously manufacture conforming products and minimise non-conforming and defective material (Halim Lim, Antony, Arshed & Albliwi, 2015; Kumar, Antony & Tiwari, 2011; Wang & Zhang, 2008; Yunus, Taib & Iteng, 2016). Productivity increases with quality as rework and scrap are minimised, thereby saving time and money (Deming, 1986). It is thus essential to manufacture a product to be 'first time right' (Lobont, Kifor, Oprean & Suciu, 2011).

Quality assurance and control form an integral link in the value chain of manufacturing defect-free products, first time right. The chemical industry relies heavily on chemical laboratories to analyse final products with defined quality control checkpoints along the process. A sampling schedule or control plan defines critical process points where testing is required to ensure a compliant product; nonetheless the identification of defective products will require additional resources to rework the material, if possible, and will increase the cost of poor quality (Harrington, 1999; Moller-Wong, 1988; Taguchi & Wu, 1979; Tsou, 2007). Material that was not identified as defective during the process will only be identified when performing final inspection. At this point sorting of conforming and non-conforming material has to take place to rework the latter (Lim & Antony, 2016), generating failure cost. It therefore follows that non-conforming products should be detected during manufacturing. Statistical Process Control (SPC) is a technique which could be used to achieve this early detection as "SPC fosters quality while the product is being produced, not afterwards" (Ali, 1992). The key is to manage risk by minimising defective material through early detection and identification (Lim & Antony, 2016).

The level of risk associated with an unwanted event is the product of the probability of the occurrence of the unwanted event and the associated severity if the event occurs (Rodríguez-Pérez & Peña-Rodríguez, 2012). In chemical manufacturing, managing the level of risk associated with process variation is critical (Chan, Jie, Kamaruddin & Azid, 2014; Cheng & Hubele, 1992; Halim Lim *et al.*, 2015; Kandananond, 2014; Kumar *et al.*, 2011). As such, Montgomery (2009) defines quality as inversely proportional to variation. Variation of critical process parameters may lead to non-conforming material, rework and the association of an inefficient process. The principles of quality engineering are focused on minimising process variability (Aljebory & Alshebeb, 2014; Montgomery, 2009). This variability can only be expressed using statistical terms.

SPC is a set of problem-solving tools with the aim of achieving and maintaining process stability and improving process capability by minimising variability, using statistics (Montgomery, 2009; Rantamäki, Tiainen & Kässi, 2013; Škulj, Vrabič, Butala & Sluga, 2013). Statistics provides a platform to evaluate the performance of a process by establishing an associated measure of goodness of a dataset and translating this into process performance (Carter, 1993).

The control chart was introduced by Dr William Shewart in 1924 at AT&T Bell Laboratories (Montgomery, 2009). In 1931, Dr Shewart published the book *Economic Control of Quality of Manufactured Product*, defining the role of statistical methods in manufacturing. Since then major contributions have been made to the quality realm by the likes of Dr William Edwards Deming, Dr Kaoru Ishikawa and Dr Joseph Juran. SPC encompasses a set of statistical techniques applied to the manufacturing process to minimise variation by indicating and predicting variation. Companies implement SPC to attain the highest degree of consistency in their processes as it permits the ability to predict variation, using process data (Ali, 1992).

SPC cannot be deployed without a clear implementation plan (Cheng & Dawson, 1998; Hsiang, 1987; Toledo, Lizarelli & Santana Junior, 2017). No 'one size fits all' blueprint exists, but a common critical requirement is management support and commitment (Grigg & Walls, 2007; Lim & Antony, 2016). Unfortunately, many have failed to successfully integrate the concept into their daily operational activities (Cheng & Dawson, 1998; Toledo *et al.*, 2017). Furthermore, SPC has been implemented with marginalised success in developing countries (Madanhire & Mbohwa, 2016). Grigg and Walls (2007) list lack of management commitment, lack of understanding of SPC and its principles, lack of understanding the purpose of SPC, lack of training, failure to interpret control charts, lack of process knowledge, the improper identification of characteristics to measure and also inadequate measuring systems as reasons why SPC fails. Toledo (2017) claims that a lack of mindfulness towards critical success factors (CSF) leads to failure of the implementation of a sustainable SPC system. SPC implementation requires cultural and organisational commitment. SPC demands commitment that transcends the technical aspects of implementation (Grigg & Walls, 2007).

Strategically, SPC requires integration into the value chain of the business process as it influences employee morale, process performance, business performance and financial performance (Krumwiede & Sheu, 1996). Buch and Dave (1993) argue that failure to sustain SPC can be attributed to changes in the strategic subsystem. The strategic subsystem is restricted to educational and managerial requirements focused on the implementation and coordination of SPC, lacking strategic intervention and a link between business objectives, the customer and market strategies (Buch & Dave, 1993).

Quality functions in Small to Medium-sized Enterprises (SMEs) are employed to guide conformance to customer specifications, but the implementation of statistical tools to enhance this ability is uncommon. The lack of resources and capability directs focus on the traditional quality functions (Kumar *et al.*, 2011; Sousa, Rodrigues & Nunes, 2017).

It is therefore clear that the successful implementation of SPC requires an environment conducive to continuous improvement. This study evaluates the organisational and methodical requirements for SPC deployment, with the focus on SMEs in South Africa. The study produces an implementation framework for SPC by surveying current implementation methodologies and frameworks. Although SPC has been established as a powerful tool for continuous quality improvement, literature lacks successful implementation strategies and approaches in chemical manufacturing processes, and even less so in a South African context (Madanhire & Mbohwa, 2016). The study aims to:

a) Evaluate existing literature on SPC implementation and identify deficiencies and critical success factors (CSFs).
b) Generate an implementation framework for SPC, which may be used as a guideline running up to the implementation of SPC, focusing on the technical and organisational aspects.

The study attempts to address the 'how to' implementation aspects of SPC by developing an implementation framework and implementing SPC as a case study in a specific manufacturing environment. The validation was performed using participatory action research as the researcher is employed in the case study environment.

1.1. Problem statement and research objectives

Despite the vast amounts of literature available on the topic of SPC and continuous improvement, literature lacks a *detailed, comprehensive and simple implementation procedure which guides the user in how to successfully implement the system as well as how to gain the most success from the effective implementation of SPC* (Sharma & Kharub, 2014a). Unfortunately, literature lacks detail regarding strategic approaches on the implementation of SPC in SMEs with limited resources. This provides little or no confidence that the

implementation of SPC will succeed. Implementation barriers are evident in the SME manufacturing environment, with these enterprises lacking technical ability and statistical proficiency (Madanhire & Mbohwa, 2016).

1.1.1. Problem statement

Buch and Dave (1993) argue that in corporations most employees are just silent while they allow premature project implementations to run their course. The lack of subsystem changes and integration of SPC into the business culture, constrains the deployment into the classic cycle of hype, plateau and decline. This occurs when SPC is pursued without the proper resources, education, methodologies and a proper understanding of the tool and its functionality. The project fails and all belief in the tool is lost and the project is abandoned, due to poor planning and an immature deployment plan.

This specific research study is driven by the desire of senior management to run a robust SPC process; however, the lack of preparation led to the immediate failure of this programme as the maiden attempt was unsuccessful. The programme was implemented with little or nothing by way of preparation with management lacking the technical knowledge to fully understand and support the programme. SPC was seen only as control charts with the former illustrated as run charts. The programme had no problem-solving supplementary. Therefore, the programme failed to reduce process variability. No prior training or raising of awareness was conducted or presented to those using the charts, thus restricting the true effectiveness of the tool. This led to the question: *Which factors contribute to the success of SPC deployment and how can SPC be implemented in an environment with limited resources?*

1.1.2. Research aim

The aim of this research is to *establish the best practice organisational and methodical requirements which have to be in place to effectively implement an operator friendly and sustainable SPC programme in a South African SME*.

1.1.3. Objectives

The primary objective of this study is to generate an implementation framework which can support the sustainable deployment of SPC in manufacturing SMEs. The challenge is to effectively structure, implement and maintain a robust strategy for SPC deployment in SMEs, by deriving and assessing existing models sourced from published literature. As such, this study will:

1. Critically review and analyse theory, tools and frameworks for CSFs relevant to the implementation of SPC.
2. Critically review and analyse theory, tools and frameworks from other CI initiatives (Six Sigma, LEAN).

3. Critically review and analyse existing company procedures and data to establish a SPC baseline.
4. Identify deficiencies in published implementation frameworks and summarise the CSFs.
5. Address the deficiencies in existing implementation strategies and tailor the solutions for South African SMEs.
6. Construct a framework for the effective and strategic implementation of SPC in chemical manufacturing SMEs, grounding the framework on the outcome of the reviewed frameworks.
7. Validate the model in the proposed environment as a case study using action research.
8. Evaluate the process performance before and after the implementation of SPC.

Upon successful implementation at the pilot site, SPC may be deployed to other facilities within the same group using the same framework. The objective is to extract valuable guidelines from literature and tailor them to the proposed environment.

1.2. Significance, limitations and ethical implications of research

1.2.1. Significance of research

Implementation studies discuss high-level detail of steps to be followed in order to deploy SPC. The challenge is implementing these frameworks in processes and identifying the critical to quality (CTQ) characteristics, which requires strict monitoring and control in order to ensure a compliant product. Various studies have been completed on the implementation of SPC in various industries. However, none of these frameworks or guidelines involves a 'how to' for process prioritisation. None of the existing frameworks elaborates on a detailed 'how to' implementation strategy for entities with limited resources at their disposal. Furthermore, SMEs do not have the capacity to employ multiple SPC champions.

The research aims to focus and provide examples on the technical aspects leading up to the implementation of SPC, highlighting the preparation phase. During this phase the 'what' and the 'how' are identified as process performance can already be influenced by identifying the appropriate characteristics and ensuring a capable measuring system, therefore influencing the effectiveness of SPC.

Existing published frameworks lack an effective method of establishing the critical to quality parameters. SPC utilises the functional form Y = F(X). Y is the dependent CTQ characteristic which requires control and X is a set of independent variables (see Figure 1), which possibly affects the output (Antony, Gijo & Childe, 2012; Hallam, Muesel & Flannery, 2010; MacGregor & Kourti, 1995). These X metrics are monitored using an SPC system to ensure a stable Y metric and provide the ability to make data-driven decisions employing statistical techniques. The aim is to establish the ability to statistically predict the trends of the Y-metric by measuring, monitoring and controlling the X-metric to ensure that the process is within statistical control. A stable process implies that the process variation can be predicted within established process limits (Ali, 1992).

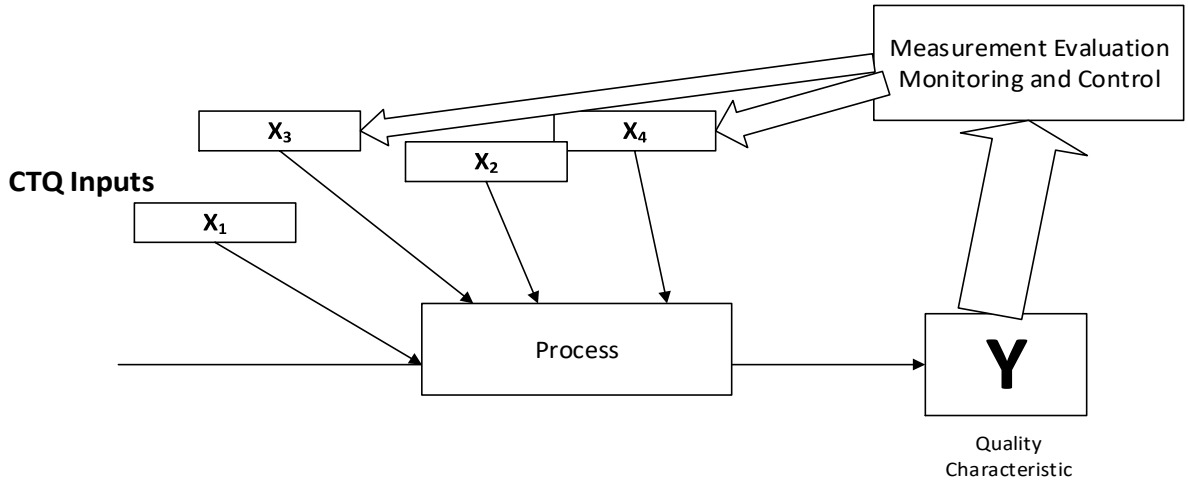


Figure 1: Production process input and outputs illustrated using the functional form Y = F(X)

Adapted from: (Beckford, 2001; Montgomery, 2009)

The ultimate goal of the research is provide a superior approach to the implementation of SPC following the failed initial attempt in the case study environment.

Management rushes implementation for results to impress senior management. This form of implementation is more concerned with the number of charts displayed instead of the quality and significance of the information to the company. This lack of 'Statistical Thinking' is still present in today's corporations. The fundamental significance of SPC, the appropriate strategic integration into the value chain and attention to detail with regards to cultural integration are not highlighted in current published articles. This mediocre and rushed approach for the deployment of SPC leads to failure, as was the situation with the case study environment. In retrospect, no groundwork and pre-implementation preparation was done.

This research attempts to close the gap by developing an operator friendly system. The system is coordinated by a single SPC Champion. The coordinator will define the critical control metrics using statistics. The research will attempt to bridge the gap between practical implementation and theory by providing a step-by-step implementation framework for the implementation and support of SPC. Therefore, emphasis is placed on the steps leading up to the implementation of SPC. If implemented successfully, SPC may:

- Increase process stability
- Minimise process variability
- Improve process performance

1.2.2. Limitations and assumptions of the study

The study is limited to existing publications on the implementation of SPC and the case study environment. The author is currently employed in a continuous chemical manufacturing SME in South Africa. As such, the author has access to facilities and data of the organisation and the implementation will thus be limited to these facilities.

1.2.3. Ethical implications of the research

The study involves collaboration with a private company. The researcher will have access to information that is not available in the public domain, but which is not linked to individuals or personal information. The information is process data which will be analysed for the purpose of the studies. All information and data gathered is confidential and the intellectual property of the proposed case study environment. Information will not be disclosed to external parties without formal consent from the company. The table below (Table 1) discusses all the relevant triggers for ethical clearance and evaluates the proposed research topics' relevance to each trigger. This study will be linked to process data that is not sensitive nor linked to any individual and therefore only qualifies for Section 3 in the table.

Table 1: Ethical clearance criteria for postgraduate students

Requirement	Description	Declaration
1.	Data collected from, or interact with, one or more individuals through interviews, surveys, focus groups, observations, video recordings etc.	No data will be collected from individuals through interviews, surveys, focus groups, observations, video or recordings or in any other manner.
2.	Access to confidential data or information of an organisation, institution, or company, where data is not available in the public domain. The data can be linked to individuals, clients, or employees.	The researcher has access to confidential data of an organisation, however the data is not linked to any individual, client or employee.
3.	Collaboration with an institution, organisation, or company that is providing access to physical or financial data that is not linked to individuals or any personal accounts or personal information. An authorised representative of the company grants access.	The researcher will collaborate with a company by using data related to manufacturing processes, which is not available in the public domain. However, the data is not linked to individuals, accounts or any personal information. An authorised representative of the company will grant authorisation for the use of this information.
4.	Access to a database or archive that holds information linked to personal identifiers.	The purpose of this study does not involved databases or archives which hold information linked to personal identifiers.
5.	Information or data is gathered which is available in a public domain. The data can be regarded as sensitive or potentially sensitive information.	The data gathered for the purpose of this study is not sensitive.

1.3. Conclusion

This chapter defines the problem statement, research aims and objectives of this research study. Furthermore, the significance, limitations and ethical implications of the research are deliberated. The following chapter reviews and summarises literature relevant to SPC and continuous improvement in support of satisfying the above mentioned research aims and objectives.

Chapter 2 – Literature review

Given the vast amounts of literature available in the domains of Quality Management and Statistical Process Control, the following chapter will review and summarise the different areas in quality management and continuous improvement and present the connection between the intended research and the existing literature.

The chapter elaborates on concepts relevant to the research study to provide an overall understanding on the content of the subsequent chapters. The review of existing implementation frameworks is performed in this chapter. This review serves as the foundation for the development of the framework for the implementation of SPC.

2.1. The interpretation of variation and statistical thinking

A fundamental trait of our everyday environment is that no subsequent event is precisely repeatable (Ali, 1992). Despite the best effort of manufacturing entities, the probability is low that two consecutive batches of material will have exactly the same characteristics (Montgomery, 2009; Yeh & Sun, 2013). Variation is inherent to any system-based process as a combination of people, materials, methods, machines and the environment contribute to a natural variation around a process mean (Ali, 1992; Beckford, 2001; Siddiqui, Saif, Cheded, Elshafei & Rahim, 2015; Toledo *et al.*, 2017; Woodall & Montgomery, 1999).

The acknowledgement of variation allows for better understanding of a process (Grigg & Walls, 2007; Rantamäki *et al.*, 2013), as it increases process knowledge by familiarising the process owner or operator with the process behaviour during specific situations (Toledo *et al.*, 2017). Deming's chain reaction model argues that a reduction in process variation initiates a chain reaction by delivering a range of positive outputs in the form of a reduction in nonconformities, wastage, scrap, cost of quality, customer complaints and improved process efficiency (Deming, 1986).

Given that management acknowledges the presence of variation, process controllers, managers and engineers are permitted to interpret variation and act accordingly. As variation can only be interpreted using statistics, the need for data-driven decision-making becomes imperative in a production environment (Halim Lim *et al.*, 2015; Hung & Sung, 2011b; Škulj *et al.*, 2013), fostering statistical thinking (ST). Grigg and Walls (2007) perceive statistical thinking as the acknowledgement that variation is inherent to processes. Furthermore, they argue that variation should be understood and statistics should be utilised when making decisions.

Montgomery (2009) defines statistics as the science of analysing and interpreting data, by acknowledging and accounting for variation in a dataset. Variation is either stable or unstable and statistics can be utilised to distinguish between the two types (Ali, 1992; Bendell, Disney & McCollin, 1999). Stable variation is a consistent oscillation about the mean of measurements taken from a process (Yunus *et al.*, 2016). This illustrates the natural process limits (UCL and LCL). Unstable variation expresses the randomness of a process, continuously changing with erratic systemic patterns (Gejdoš, 2015; Goh & Xie, 2003; Madanhire & Mbohwa, 2016; Yunus *et al.*, 2016). Using control charts, variation can be isolated by identifying these specific patterns (Duffuaa, Khursheed & Noman, 2004). The cause of variation can be classified as either common cause variation or assignable cause variation (Ali, 1992; Goh & Xie, 2003; Grigg & Walls, 2007; Montgomery, 2009; Sharma & Kharub, 2014b; Siddiqui *et al.*, 2015).

Common cause variation – This entails natural fluctuation around the process mean indicating inherent and stable variation. No process adjustment is required for this natural variation (Ali, 1992). This variation can be reduced by installing a fundamental process change as this is the natural state of the process (Gejdoš, 2015). Operators trained in SPC can distinguish between common and assignable cause to prohibit unnecessary process adjustments, as this may have a severely negative effect on the process performance and product quality (Grigg & Walls, 2007).

Assignable cause variation – This variation is out of the ordinary and requires problem-solving tools in order to identify the source of the variation (Grigg & Walls, 2007). This variation contains outliers or specific trends in the dataset, which is the root of unstable variation. Assignable cause variations display unusual trends and thus it is required to look for 'unusual root causes' to this type of variation (Ali, 1992; Chen & Cheng, 2011; Woodall & Montgomery, 1999). Once the source has been identified an input variable or a possible process parameter can be adjusted to regulate the variation and return the process to its natural state (Gejdoš, 2015).

Equally important to understanding the difference between common and assignable causes for SPC implementation is a precise measuring system. Halim Lim *et al.*(2015) highlights the lack of an accurate and trustworthy measurement system as a barrier for successful SPC implementation. A validated and capable measuring system is a fundamental necessity to ensure that the user observes true part-to-part or process variation, which is not influenced by an inadequate measurement (Hsiang, 1987; Rantamäki *et al.*, 2013).

2.2. Measurement systems analysis

The AIAG (2010) defines measurement as the practice of assigning values to material things to represent relationships of specific properties. The measurement value is the assigned value and the process of obtaining the value is the measurement process.

Data-driven decision-making offers confidence in the approach to decisions, which affects processes and products as it is based on statistics and measured performance. However, the quality of the data has a significant effect on the quality of the decision. Adjusting processes unnecessarily negatively affects the process and may lead to the manufacturing of defective material. The emphasis on the quality of the measurement allows for useful decision-making, which will benefit the process. Variation and bias are the two common properties which are used to characterise a measurement or the quality of a measurement (AIAG, 2010). Variation involves the spread of a dataset where bias relates the measured averages to a reference value.

Measurement system analysis (MSA) involves the validation of the measuring system. MSA aims to quantify and isolate the observed variation in order to identify the source of variability of the measuring system, if present. This is done by evaluating the accuracy and precision of the measuring system therefore assessing the suitability of a measuring system for the specific purpose (Pyzdek & Keller, 2010). MSA distinguishes and isolates the part-to-part variation from the measurement system variation (Yeh & Sun, 2013).

Measurement system variation is caused by errors in measuring equipment, measuring methods, operators and lab analysts (Yeh & Sun, 2013). To maximise favourable decision-making using data, the quality of the data should be assured by focusing on the removal of measurement system variation. Bias can be minimised by calibrating and verifying equipment at set intervals (AIAG, 2010).

Measurement system analysis focuses on precision and accuracy. The total variation observed by the user is illustrated in Figure 2.

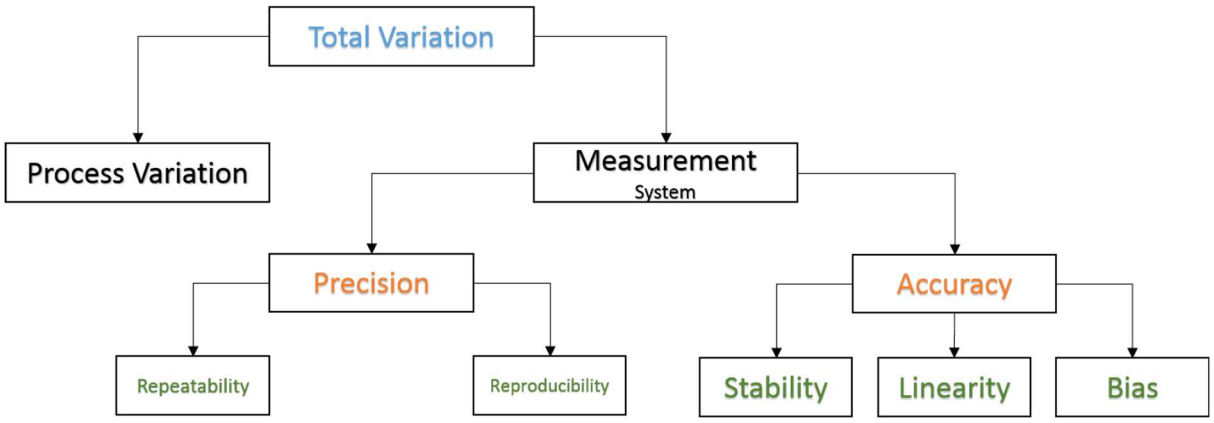


Figure 2: The breakdown of observed variation adapted

Adapted from: (Yeh & Sun, 2013)

Figure 2 can also be expressed as:

Equation 1: Observed variation formulation

$$\sigma^2_{total} = \sigma^2_{process} + \sigma^2_{measurement\ system}$$

Source: (Montgomery, 2009)

Measurement system variation can be decomposed into:

Equation 2: GRR decomposed into repeatability and reproducibility

$$\sigma^2_{GRR} = \sigma^2_{reproducibility} + \sigma^2_{repeatability}$$

Source: (Doshi & Desai, 2019)

2.2.1. Precision

Precision evaluates the variance of a sample or measurement relative to its dataset, implying the closeness of repeated measurements to each other (AIAG, 2010). A precise metric returns the same value repeatedly. The precision of the measuring system can be evaluated by performing a gauge repeatability and reproducibility (GRR) test (Antony *et al.*, 2012). This study aims to identify and isolate variation caused by the measuring system and variation caused by the appraiser or operator (Doshi & Desai, 2019).

Repeatability

Repeatability is the variation obtained with measuring a sample or characteristic with exactly the same method and the same appraiser, repeatedly (Does, Trip & Schippers, 1997; Yeh & Sun, 2013). Repeatability identifies variation, which is contributed by the gauge or the measuring method.

Reproducibility

Reproducibility is the variation obtained when trying to reproduce the same measurement by allowing different appraisers, using the same method, to measure a sample or characteristic (Does *et al.*, 1997; Yeh & Sun, 2013). Reproducibility identifies variation, which is contributed by the appraiser or analyst.

General acceptance estimates of the GRR value used to evaluate the capability of the measurement system are (AIAG, 2010; Doshi & Desai, 2019):

- Deemed acceptable if less than 10%.
- Marginally acceptable if between 10% and 30%.
- Unacceptable if GRR exceeds 30%.

2.2.2. Accuracy

Accuracy is the bias between the returned value and the true value (Pai, Yeh & Hung, 2015). Accuracy is the ability of a measuring instrument to return the true value. Errors which affect the accuracy of a measurement system are stability, linearity and bias (Montgomery, 2009; Pai *et al.*, 2015).

Bias

Bias, as illustrated in Figure 3, is the difference in measurement value between the observed measurement averages and the reference value (AIAG, 2010; Pai *et al.*, 2015).

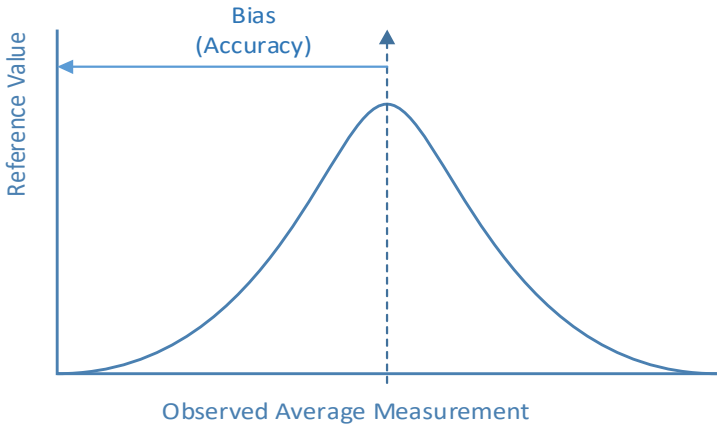


Figure 3: Graphical illustration of measurement bias

Source: (AIAG, 2010)

Stability

Stability is the change in bias when measuring a single characteristic over an extended period of time (AIAG, 2010).

Linearity

Linearity is the change in bias within the normal operating range of a gauge (AIAG, 2010). Figure 4 illustrates a linearity test performed on a scale.

Linearity Test

Certificate Value of Load Applied kg	Scale Indication kg		Error kg
	Before Adjustment	After Adjustment	
200,0	199,0	-	1,0
400,0	399,0	-	1,0
600,0	599,0	-	1,0
800,0	799,0	-	1,0
1 000,0	1 000,0	-	0,0

Note 1: User must make corrections for linearity errors, if required, when using the scale.
Note 2: No adjustment was made to the scale.
Note 3: Partial Calibration – Linearity only done up to 1 000 kg.

Figure 4: Example of the linearity test performed on a scale

The Automotive Industry Action Group (2010) highlights four aspects which are critical when classifying a measurement system as acceptable. The measurement system should have adequate sensitivity to be able to identify and discriminate for different levels of the characteristic. Coupled with adequate sensitivity, the measurement system should be within statistical control. Essential for both product and process control, the variation of the measurement systems should be acceptably small within the product characteristic tolerance and the process characteristic tolerance. Therefore the measurement system should be assessed against the product tolerance and a six sigma spread of the process characteristic. The above-mentioned criteria are all assessed when performing a measurement system capability study.

Once the measurement system capability has been deemed acceptable the process capability can be evaluated. The measurement system capability is a short-term estimate of the measurement system variation using metrics such as the GRR, whereas the measurement system performance is a long-term estimation of the measurement system variation (AIAG, 2010).

2.3. Process capability

Process capability analysis is a method used to statistically evaluate the performance of a process within established limits (Montgomery, 2009). The process capability analysis estimates the level of control of a process within the specification limits (Does *et al.*, 1997). If a process is within statistical control, a capability analysis can be performed which assesses the ability to predict the amount of defective products per million opportunities (DPMO). Normal distribution plots illustrate the process capability using histograms (Bell Curves).

Sample size affects the results generated during a capability study. It is generally encouraged to have at least 40 samples for a capability analysis to ensure stable and reliable estimation of process capability (Montgomery, 2009). A smaller sample size might portray a process as very capable (or not capable), which might instil false confidence and lead to the manufacturing of defective material.

The calculated process capability indices quantify the ratio between the specification limits and the inherent process variation (C_p). It illustrates how well the measured dataset fits into the process specification limits. The process capability index also considers the position of the distribution by estimating the deviation of the specification target mean to the actual process mean (C_{pk}). The C_p and C_{pk} are based on the contractual requirements agreed between the supplier and the customer (Does *et al.*, 1997; Montgomery, 2009; Sharma & Kharub, 2014b). A basic and general description of process capability and centring index values, relative to the estimated performance of the process can be observed in Table 2. The index values calculated are applicable as agreed upon internally or between the supplier and client.

Table 2: Process performance estimation based on capability indices

Capability Index	Estimated Process Performance
$C_{pk} = C_p$	Process mean is equal to centre of tolerance (process is centred)
$C_{p < 1}$	Process is not capable and requires improvement
$C_{p = 1}$	Process is minimally capable
$C_{p > 1.33}$	Good process capability
$C_{p > 1.66}$	Excellent process capability
$C_{pk} \neq C_p$	Process mean is off-centred

Adapted from: (Sharma & Kharub, 2014b)

Therefore, the process capability plays a significant role in variation reduction and will be used to evaluate process performance in this research study. The variation in processes and the drive to minimise the manufacturing of defective products by developing capable processes has seen various quality gurus contribute to this domain and shape the world of quality management as we see it today.

2.4. The evolution of quality and SPC – A brief overview

Maximising monetary gain by fulfilling the needs of a customer is an age-old adage. The ideal of customer satisfaction and economic gratification was established prior to the concept of any management system or tool when a simple artisan exchanged a product for economic enhancement (Weckenmann *et al.*, 2015).

Prior to 1900, Frederick W Taylor introduced scientific management to high volume manufacturing (mass production). His philosophy was characterised by the separation of the production planning and the execution thereof by observing, measuring and analysing each task. He standardised tasks with the aim of simplifying the assembling of components. This led to substantial improvements in productivity and the quality of all manufactured goods. The concept of work standards was born (Locke, 1982). Henry Ford developed the assembly line concept between 1900 and 1930, where he introduced mistake proof assembly concepts using in-process inspections and self-checking. (Montgomery, 2009; Weckenmann *et al.*, 2015).

The initial attempt to use statistical quality control methods in processes was partly established in the 1800s by statistician and technologist W.S Gosset, while working for Guinness Breweries (Abdul Halim Lim & Antony, 2013; Grigg & Walls, 2007). Statistical methods and their application were, however, pioneered by Walter A. Shewart in the 1920s (Ali, 1992; Hubbard, 2003; Montgomery, 2009). Shewart was an engineer at Bell Telephone Laboratories and developed the statistical control chart concept for quality improvement (Hallam *et al.*, 2010; Montgomery, 2009). Shewart took process data and graphically arranged the points into a chart which is known today as the 'P' chart (Ali, 1992). He also developed the concept of statistically based

sampling instead of 100% inspection (Lahidji & Tucker, 2016). The idea of statistical quality control took off and was implemented by Western Electrical, but diffusion of this innovation never reached the exponential growth phase and was never fully recognised by the industry.

Between 1940 and 1960, an increased use of statistical quality control was evident during World War ll (Toledo *et al.*, 2017). Post World War ll saw the dominance of the US car market running almost unopposed, but with a low quality product (Lahidji & Tucker, 2016). There was a demand for quality and productivity and set guidelines were implemented to ensure that these principles were executed. The American Society for Quality Control was established and led to further expansions of the Quality Management Concept. The view of quality as a management initiative was introduced and organisations started utilising management systems to enhance their manufacturing capability (Montgomery, 2009).

Walter E Deming's view on quality management revolutionised the industry. Deming encouraged the use of statistical methods in quality control by building on the principles of Shewart (Abdul Halim Lim & Antony, 2013; Hallam *et al.*, 2010). He adopted and furthered the basis of quality concepts started by Shewart and used these techniques to help the Japanese make use of statistical process control in their automotive industry (Hallam *et al.*, 2010), an automotive industry that was struggling to compete with the US due to a shortage of raw materials, capital and labour (Lahidji & Tucker, 2016). Deming introduced industrial and statistical quality control in Japan, which revolutionised the manufacturing strategies and transformed the Japanese manufacturing paradigm by making them the leaders in bulk manufacturing of automotive vehicles. With the assistance of Deming, Eiji Toyoda developed the Toyota Production System (TPS) which changed their reputation to one that was associated with quality and performance (Hallam *et al.*, 2010). By the mid-1970s the dominance of the Japanese car market was evident, steered by the TPS (Lahidji & Tucker, 2016). Ideas for the TPS were developed between 1929 and 1940, where Taichi Ohno and Eiji Toyoda studied the production process and management techniques of the American Ford Rouge Plant (Hallam *et al.*, 2010). Ohno and Eiji labelled the Ford production process as inefficient, which led to the manufacturing of poor quality parts and thus expanded on TPS by incorporating techniques developed in the USA.

The 1980s saw the work of quality gurus such as G Taguchi and K Ishikawa introduce the Design of Experiments (DOE) Concept and The Cause and Effect Diagram, also known as the Ishikhawa diagram (Ali, 1992; Beckford, 2001). The drive for continuous improvement and cost reduction saw philosophies such as Six Sigma and Lean surface. Six Sigma was introduced in the 1980s by Motorola as a continuous improvement tool and has since become an established tool for driving continuous improvement in companies (Antony *et al.*, 2012; Chan *et al.*, 2014). The TPS was introduced as "Lean" production as MIT developed the International Motor Vehicle Project (IMVP) (Lahidji & Tucker, 2016).

The application of Statistics in Quality Control was well documented throughout the 1900s. Quality ceased to just be an operational extra and became imperative to business realisation in a saturated market environment with peculiar clients (Beckford, 2001). It evolved from an operational extra into a significant component of holistic operational management. The aim ultimately remained customer satisfaction, utilising the most effective techniques to ensure the most efficient and cost-effective process.

2.5. Quality viewpoints

Quality considers different viewpoints. Customers desire products and services of superior quality and generally at the cheapest price with the shortest lead time, summarised as QCD – Quality, Cost and Delivery (see Figure 5). Efficiency is delivering these aspects or exceeding them as the customer requires them, viewed as the perceived customer value. A manufacturer aims to produce a superior product at the lowest cost. Quality Management Systems (QMS) and continuous improvement initiatives are implemented for these exact reasons and manufacturing units strive to achieve the set goals. This is efficiency from the manufacturer's perspective. A QMS governs the systems used to manufacture goods and clients are attracted to manufacturers with a QMS as it provides assurance of a quality product. Pyzdek and Keller (2010) state that "Excellent processes are those that are both effective and efficient".

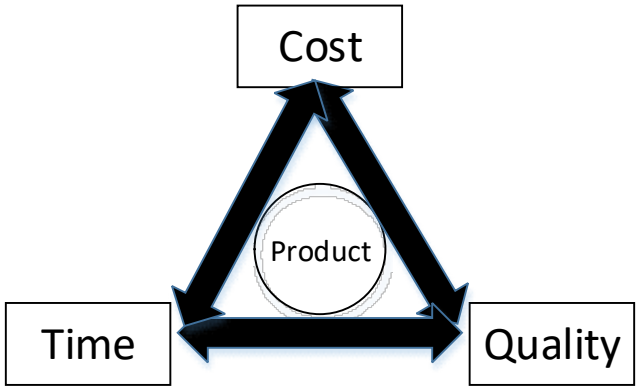


Figure 5: Linkage between quality, cost and time

Adapted from: (Weckenmann *et al.*, 2015)

The different viewpoints can be assessed using Garvin's (Garvin, 1987) dimensions of Quality. Modern businesses define specific strategic guidelines to assure successful implementation of their Quality Management System (QMS). According to Garvin (1987), the quality of a manufactured product can be described in several ways. Garvin proposed the eight dimensions of quality (see Table 3), which can be employed as a strategic approach to assess Quality in a corporation.

Table 3: The eight dimensions of quality

Dimension	Description
Performance	Product performance is evaluated against the intended design objective of the product or its primary characteristics, as agreed upon by the customer or client. Simply stated, this is how well the product performs.
Reliability	The reliability of a product is the ability to function under specified conditions for a defined time duration. Reliability considers the frequency of failures. Equipment manufacturers are evaluated in accordance with the reliability of their product. Typical measures include: mean time to first failure, mean time between subsequent failures and the failure rate (per unit time). Reliability entails the operational period until a product requires maintenance.
Durability	The durability is the lifespan of a product or component. Customers desire products that perform well for a prolonged period before a replacement unit is required. Durability thus considers the period until a product is obsolete.
Serviceability	The serviceability is the ease and simplicity of the service process as a whole. This is determined by the speed, competence, courtesy and effort involved of the service provider with the repair or correction. The likelihood of returning to a service provider is dependent on prior experiences.
Aesthetics	Aesthetics is the perception of the customer regarding appearance, taste and smell of the specific product or service. This dimension is subjective and varies based on the consumer's view.
Features	Secondary aspects of product performance typically increase positive customer perception. In most situations, 'more might be better'. Quality is therefore measured on additional features against set primary characteristics when comparing similar components or products.
Perceived Quality	The reputation of the company or product influences the perceived quality view of the customers. Established brands will be preferred when the compered to a lesser known brand.
Conformance to Standards	The comparison between final product and the promised delivery. Quality is majorly governed by satisfying the customer needs, thus delivering on what was agreed to. The product is measured against the pre-established agreement between the designer or supplier and the customer. In the case of an assembly component, a deviation from the agreed-upon design will lead to complications with the final conformance.

Adapted From: (Garvin, 1987; Montgomery, 2009; Russell & Taylor, 2011)

The above-mentioned viewpoints and dimensions are all aspects that an organisation will aim to achieve at the lowest cost. The association between improvement of quality and the cost involved should be clearly

defined (Arabian, Mehdi Jourabchi, Leman & Ismail, 2013). The objective of continuous improvement is not only to meet customer satisfaction but also to do it at the lowest possible cost (Hung & Sung, 2011b; Vaxevanidis & Petropoulos, 2008). Given this, a corporation should adapt a framework to classify the cost associated with quality (Grigg & Walls, 2007; Vaxevanidis & Petropoulos, 2008).

2.6. Cost of quality (COQ)

Dr Armand V Feigenbaum, then the operations and quality manager at General Electric (Beckford, 2001), established the "cost of quality" (COQ) concept in 1943. The COQ divides the cost related to quality into four segments:

- Internal cost of failure
- External cost of failure
- Prevention cost
- Appraisal cost

(Arabian *et al.*, 2013; Harrington, 1999).

His aim was to develop an organisation-wide measuring system of costing by incorporating all cost related to developing systems for product quality, quality control costs (inspections) and the cost of producing non-conforming material. The report was quantified in a monetary value and submitted to management, which gained their attention as (according to Feigenbaum) money is the language of management (Arabian *et al.*, 2013; Harrington, 1999).

The term "Cost of Poor Quality" was used to ensure that no negative connotation is associated with the term "Quality Cost". Feigenbaum believed that by allocating sufficient funds to preventive cost, ensuring conforming outputs, external and internal failure cost may be reduced, ensuring increased profit (Beckford, 2001). The COQ can be divided into the Cost of Poor Quality (COPQ) and the Cost of Good Quality. The COPQ consists of the internal and external cost of failure, while the cost of good quality consists of the prevention and appraisal costs.

2.6.1. Cost of Poor Quality

2.6.1.1. Internal cost of failure

Internal failure costs are incurred when defective products are manufactured. Rework and retesting costs are incurred when a material has been identified as defective, but additional time, money and labour are spent to ensure that the final product conforms after being reworked. Costs are not only incurred by the additional value added to the material, but also due the production scheduling delays of reworking material (Arabian *et al.*, 2013; Beckford, 2001; Harrington, 1999; Montgomery, 2009; Vaxevanidis & Petropoulos, 2008). The manufacture of potentially conforming product is delayed, and this could lead to delivery delays as the production and delivery schedule is adjusted to compensate for time wasted on rework. Failure to

rework material could generate scrap cost, as no value is gained from the material, yet a cost is incurred as the final product has a book value that needs to be scrapped due to non-compliance

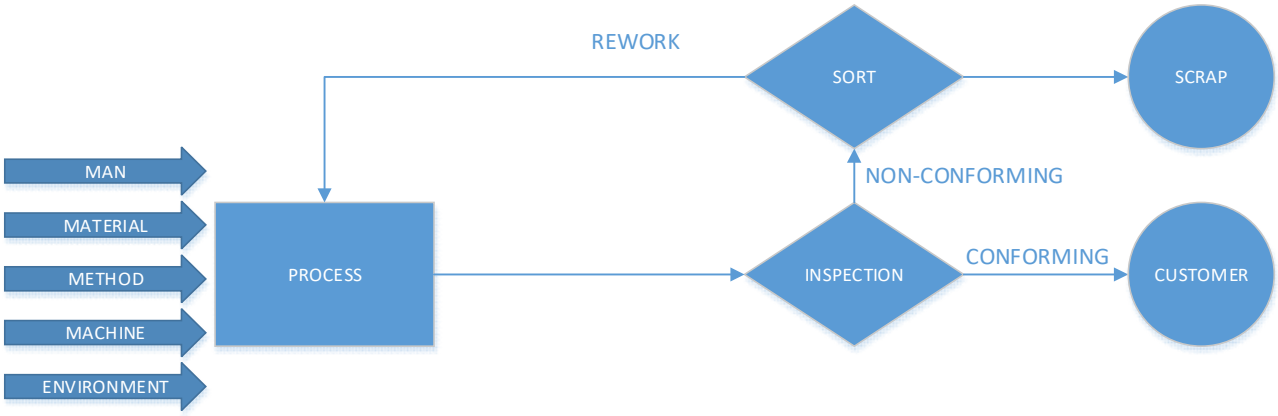


Figure 6: Flow diagram illustrating inspection-based system and failure cost generation

Adapted From: (Antony & Taner, 2003)

2.6.1.2. External cost of failure

Costs associated with external failures are incurred when defects are identified post-delivery to the customer, and within the guaranteed shelf life period or due to customer dissatisfaction (Arabian *et al.*, 2013; Beckford, 2001; Harrington, 1999; Montgomery, 2009; Vaxevanidis & Petropoulos, 2008). Depending on the contractual agreement, the supplier could be held liable for any costs incurred with reworking of the material or the scrapping of the non-conforming product. The customer can also hold the supplier liable for any penalties suffered on their deliveries due to a delay in their process, as the non-conforming material contributed to planning delays in the customer process, or any loss in sales or potential sales (Arabian *et al.*, 2013; Beckford, 2001; Harrington, 1999; Montgomery, 2009; Vaxevanidis & Petropoulos, 2008).

2.6.2. Cost of Good Quality

2.6.2.1. Prevention cost

Prevention costs are costs incurred through validation and ensuring conformance. These costs are related to process changes, quality training, maintenance and resources. The cost is devoted to the security built into the value chain that ensures a satisfied customer (Arabian *et al.*, 2013; Beckford, 2001; Harrington, 1999; Montgomery, 2009; Vaxevanidis & Petropoulos, 2008).

2.6.2.2. Appraisal cost

Appraisal costs are incurred by measuring or inspecting material to ensure conformance. This involves sampling, auditing, calibration and monitoring, problem-solving and all inspections verifying conformance prior to delivery (Arabian *et al.*, 2013; Beckford, 2001; Harrington, 1999; Montgomery, 2009; Vaxevanidis & Petropoulos, 2008).

The continuous drive for operational excellence and cost reduction while minimising defective products has emphasised the importance of employing statistical techniques in the manufacturing realm (Ali, 1992). With process data being readily available, process owners can utilise statistical thinking and make use of statistical process control to assist with continuous improvement and the establishment of operational excellence. SPC and statistical quality control have been around since the early 1920s, yet the relevance and importance of the tool in the manufacturing industry has not diminished. Although feedback control loops are built into logic control systems to regulate process parameters, these control systems cannot distinguish between common and assignable cause variation and will compensate for the latter by overadjusting a process parameter to ensure the process stays within the specification limits (MacGregor & Kourti, 1995; Rantamäki *et al.*, 2013). However, the source of the variation will not be removed, and it is still up to human intervention to the restore the process to its natural state.

2.7. Statistical Process Control (SPC)

2.7.1. Overview

"….objective of statistics is to make an inference about a population based on information contained in a sample and to prove an associate measure of goodness" (Carter, 1993).

The rise of quality management saw SPC transcend the manufacturing domain. Literature supports the success of implemented SPC programmes in machining and assembly (Zhang & Yang, 2009); the food manufacturing industry (Abdul Halim Lim & Antony, 2013); heating, ventilation and air-conditioning (Siddiqui *et al.*, 2015); maintenance and reliability (Prabhuswamy, Nagesh & Ravikumar, 2013); software development (Mahanti & Evans, 2012); medicine (Gerard, Grandhaye, Marchesi, Aletti, Husson, Noel & Kafrouni, 2009), and project management (Colin & Vanhoucke, 2015).The industry diversification of SPC implementation supports Kumar and Motwani's (1996) affirmation of the economic efficiency, which an SPC system brings to the decision-making of processes.

The introduction of statistical methods into the quality management system has revolutionised how manufacturing companies operate (Hung & Sung, 2011b). An increasing number of companies are utilising various continuous improvement tools to enhance customer satisfaction (Amasaka, 2013; Antony, Kumar & Labib, 2008; Toledo *et al.*, 2017; Yunus *et al.*, 2016). Grigg & Walls (2007) argue that companies are motivated to implement a statistical control tool for two main reasons; the proactive desire to develop a competitive edge and to realise specific operational benefits. These benefits are driven by a reduction in variation that might increase efficiency, improve quality and also reduce operational cost (Toledo *et al.*, 2017).

The contributions of Stewart, Deming and Juran (amongst others) to statistical quality control and process control have provided the basis to establish and maintain stable and controlled industrial processes. The application of variance analysis has been crucial to understanding, optimising and controlling complex industrial processes (Bendell *et al.*, 1999). Observing, controlling and managing process variation is a key aspect in maintaining a high quality rate in chemical manufacturing. A stable process implies that the process variation can be predicted within established process limits (Ali, 1992).

The primary benefit of SPC is the establishment of the ability to identify and remove assignable cause variation, assuring the consistent manufacturing of compliant products (Besseris, 2013). The tool also allows for better understanding of a process as a better understanding is required of the inputs and outputs of a process to ensure effective implementation of SPC. The statistical nature of the tool allows for the collection of vast amounts of data. Historic data can be beneficial by establishing performance benchmarks which allow for improvement (Toledo *et al.*, 2017). Statistical process control requires a specific and logical thought process for effective implementation. Antony & Taner (2003) argue that employing the incorrect methodology when implementing an SPC programme contributes largely to the lack of SPC success in companies. Therefore, it is essential to employ the correct methods when implementing SPC. This increases the potential value which could be gained by implementing SPC.

2.7.2. Seven tools of SPC

The tool most associated with SPC is control charts. However, control charts are only one of seven SPC problem-solving tools (Montgomery, 2009). A general perception exists that SPC is the deployment of control charts on the manufacturing line; however, the control chart is a method used to statistically differentiate between assignable cause and common cause variation and it is necessary to employ additional tools to identify the origin of the adverse change in the process (Antony & Taner, 2003). This skewed perception contributed to the failure of the initial SPC deployment in the case study environment. A successful SPC programme incorporates all seven SPC problem-solving initiatives and is well integrated into the problem-solving routines of an organisation which strives for an environment conducive to continuous improvement (Antony & Taner, 2003; Awaj, Singh & Amedie, 2013; Mirzaei, Niroomand & Zare, 2016; Montgomery, 2009). The tools are discussed below.

2.7.2.1. Pareto analysis

Pareto charts are used to generate frequency distribution plots of attribute and continuous data of the process under investigation (Awaj *et al.*, 2013; Mirzaei *et al.*, 2016; Rantamäki *et al.*, 2013). Pareto charts illustrate the most frequently occurring issue in a process. Therefore, it is a commonly used tool in problem-solving.

2.7.2.2. Cause-and-Effect diagram (Fishbone)

Cause-and-Effect diagram (Isikhawa) is a tool used to formally elaborate on an identified problem (Awaj *et al.*, 2013). This tool is utilised to brainstorm and generate possible root causes of the problem, by the established problem-solving team (Rantamäki *et al.*, 2013).

2.7.2.3. Scatter diagram and multivariate charts

Scatter diagrams are utilised to establish relationships between two different variables, whereas multivariate charts investigate the possible relationships between multiple variables (Montgomery, 2009). The variables are plotted to evaluate the dataset for a possible correlation between the two variables to assist with problem-solving. Using regression modelling, causal relationships are identified which aid the problem-solving process.

2.7.2.4. Checklists/Check sheets

Check sheets are used to collect historical data of a specific process with specific time stamps (Mirzaei *et al.*, 2016). A check sheet logs operating data of the process under investigation and is an efficient manner to collect data of the process under investigation. This is still a very common method used to monitor and collect data of processes.

2.7.2.5. Control charts

Discussed in 2.7.3.

2.7.2.6. Defect concentration diagram

A defect concentration diagram is a graphical illustration of all the relevant views of a specific unit. All the possible defects are included in the illustration with the aim of using the location of the defect to assist with the possible identification of a probable root cause (Montgomery, 2009).

2.7.2.7. Histogram

The histogram is a compact summary of data, usually classed into intervals or bins. Measurements are displayed as frequencies illustrating the dataset as a frequency distribution plot (Montgomery, 2009).

2.7.3. Control charts

Control charts graphically display a specified monitored characteristic, which is generally critical to quality and requires constant monitoring. The data under investigation is used to generate a UCL and LCL. A process that is stable and statistically in control will show natural variation between these two control limits without coming within one standard deviation of the UCL or LCL (Montgomery, 2009; Montgomery & Runger, 2007). The control chart is employed as a process monitoring technique and by using sample averages, it can identify sources of variability by graphically displaying these averages against a UCL and LCL governed by the dataset (Latzko, 2003; Mahanti & Evans, 2012; Toledo *et al.*, 2017). These out-of-control points will trigger an investigation into the erratic process variation and actions will be taken to remove the sources of variation

and restore the process to its natural state (Ali, 1992; Toledo *et al.*, 2017). As mentioned earlier, charting is used to identify assignable cause variation. The control chart is most widely used to determine if processes are stable and predictable (Latzko, 2003) . The control chart has been successfully implemented to reduce variability (Hung & Sung, 2011a; Rantamäki *et al.*, 2013; Sultana, Science, Road, Razive, Tower & Azeem, 2009). Sample averages are used to signal the need for process adjustments by assisting in the detection of assignable cause variation (Montgomery, 2009). The control chart is thus used to distinguish between assignable and common cause variation using various charting techniques.

2.7.3.1. Benefits of control charts

The benefits of using control charts as highlighted by Montgomery & Runger (2007) are:

Effective in defect prevention and improving productivity

Control charts identify process deviations during manufacturing. This minimises the adverse effects on final products caused by unforeseen deviations by minimising variability (Montgomery, 2009). Subsequently the control chart contributes to attaining the highest degree of consistency of the process by allowing the process deviations to be identified, which then allows for the initiation of a root cause investigation in order to nullify and prevent the deviation from reoccurring (Ali, 1992). The prevention of deviations assures more plant availability to manufacture planned product, an increased quality rate and better adherence to the production schedule, which indicates a more efficient and productive process.

Prevent unnecessary process adjustment

The control chart is measured on the principle of identifying the type of variation around a predetermined process mean. In Section 2.7.3.4 the criteria which should trigger an operator to acknowledge the variation as assignable cause variation are identified. Only in this instance is it expected of an operator to act and address the variation. Common-cause variation is seen as 'inherent' variation, therefore the operator does not need to take action in these situations. Unnecessary process adjustments are addressed as the operator or process controller will be sensitised on process variation.

Provide diagnostic information

Control charts use process averages and individual readings to generate LCL and UCL by plotting the data against the calculated process mean and within a six sigma distribution. The control chart can be used to provide information on process deviations as it is time sensitive, by serving as a diagnostic tool to review the occurrence and severity of process deviations.

Provide information regarding process capability

As mentioned in Section 2.3, the process capability can only be estimated once a process is statistically in control. Conforming control charts are a requirement to proceed with the capability analysis.

2.7.3.2. Control chart selection using Shewart control charts

The control chart selection is based on the type of data used, and the most widely used control charts are the Shewart control charts (Figure 7). Data can be continuous, attribute, individual measurements or divided into subgroups (Latzko, 2003).

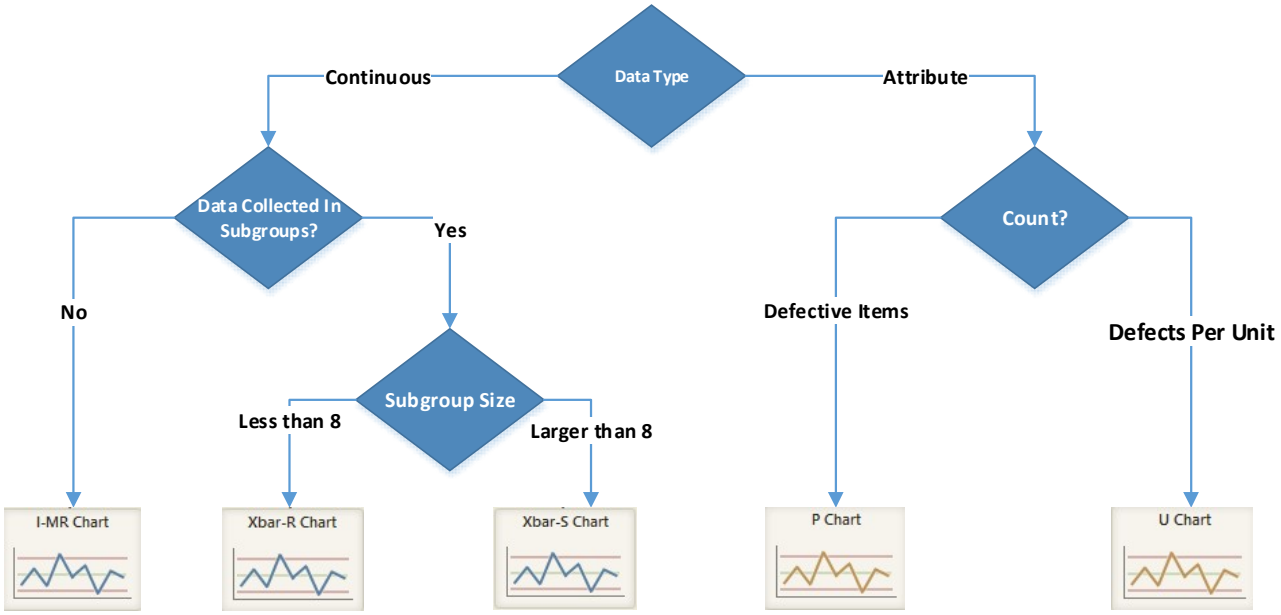


Figure 7: Control chart selection criteria

Adapted From: (Latzko, 2003)

Control charts are presented as illustrated in Figure 7 above, with data points generally oscillating around a mean.

2.7.3.3. Time-weighted control charts – Cumulative sum control charts (CUSUM) and exponentially weighted moving average control charts (EWMA)

The charts illustrated in Figure 7 are Shewart control charts which are very effective when attempting to identify large process shifts and assignable cause variation. The Shewart charts operate within a specific sample sequence and measure two successive samples against one another when calculating the magnitude of the process shift. It is therefore evident that Shewart charts do not consider the complete dataset when estimating process shifts. Shewart charts can therefore not differentiate or identify very small shifts in process change very accurately. When attempting to identify small shifts in process behaviour the CUSUM and EWMA control charts are very effective (AIAG, 2005; Montgomery, 2009).

CUSUM control charts

The cumulative control chart plots the cumulative deviations of successive sample means, from a target value. This makes it easier to identify small process shifts (AIAG, 2005; Montgomery, 2009; Montgomery &

Runger, 2007). These types of charts give equal weight to the whole dataset, but are very technical and complex to implement and interpret.

EWMA control charts

The exponentially weighted moving average (EWMA) chart is a control chart which monitors a dataset based on averages, with the weight of a subgroup decreasing over time (Montgomery, 2009; Montgomery & Runger, 2007). Therefore, the most recent process statistic will carry the most weight. This trait of the chart makes it very sensitive to small process shifts.

The value of control charts can only be experienced when applied in the correct manner. Choosing the correct control chart is critical to appropriately interpret the dataset. However, realising when to respond is fundamental in order to have the desired effect on the process. The following section contains generic rules to be aware of, but it is also critical to understand the process and how it reacts.

2.7.3.4. Out-of-control criteria

The criteria below are used to not only trigger the operator of the presence of assignable cause variation, but also to make the operator aware of when the variation is only caused by natural process variation. Figure 29 illustrates the zones mentioned in the section below in order to gain a better understanding on how to interpret Shewart control charts.

1. One or more points outside of the control limits.
2. Two or three consecutive points outside the two-sigma warning limits but still inside the control limits.
3. Four or five consecutive points beyond the one-sigma limits.
4. A run of eight consecutive points on one side of the centre line.
5. Six points in a row steadily increasing or decreasing.
6. Fifteen points in a row in zone C (both above and below the centre line).
7. Fourteen points in a row alternating up and down.
8. Eight points in a row on both sides of the centre line with none in zone C.
9. An unusual or non-random pattern in the data.
10. One or more points near a warning or control limit.

(Antony & Taner, 2003; Romdhane, Badreddine & Sansa, 2017; Sharma & Kharub, 2014b).

The out-of-control points can be followed up by an out-of-control plan to effectively address process complications.

2.7.3.5. Out-of-control action plan

The effective implementation of SPC requires the effective utilisation of control charts, which may only be beneficial to an organisation if knowledge exists as to how to react when assignable cause variation is detected (Does *et al.*, 1997). The out-of-control action plan (OCAP) is a set of pre-established actions providing operators with the diagnostic capability to determine the cause of assignable cause variation (out-of-control point) and to identify the necessary steps and actions to address and nullify the root cause (Does *et al.*, 1997).

An out-of-control action plan (OCAP) is established by a cross-functional team to aid in rapid problem-solving once assignable cause variation is identified (Abdul Halim Lim, Antony, Garza-Reyes & Arshed, 2015). The corrective actions are set in place by the SPC team to counteract the effects brought about by the cause of the assignable cause variation. The team evaluates all the possible failures and their causes. This is documented as an easily readable document by the operators and owners of the SPC programme. Figure 8 illustrates the general SPC cycle when measuring and monitoring a characteristic also illustrating the role of the OCAP in the cycle.

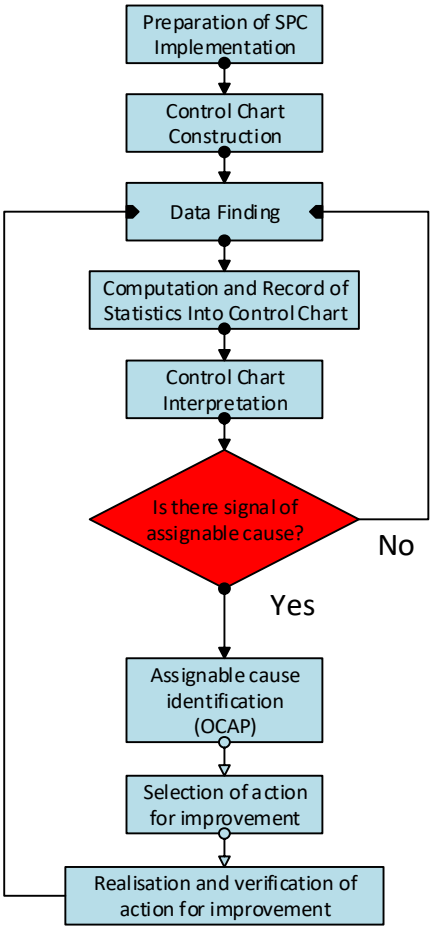


Figure 8: General SPC cycle

Source: (Noskievičová, 2010)

Failure modes and effects analysis (FMEA) is a tool used to document and anticipate process failure. Therefore, it is greatly relevant when problem solving.

2.8. Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) is a procedure utilised and established by the USA Department of Defence (USA DOD, 1980) to:

"… systematically evaluate and document, by item failure mode analysis, the potential impact of each functional hardware failure on mission success, personnel and system safety, system performance, maintainability, and maintenance requirement."

Pyzdek and Keller (2010) describe the FMEA as an outline which details all possible failures, the severity of the failure on the system (see Table 22 – 'Sev'), the likelihood (see Table 22 – 'Occ') that the failure might occur and the probability that the failure might go undetected (see Table 22 – 'Det'). The product of these components generates the risk priority number (see Table 22– 'RPN'), as illustrated below. The RPN highlights the level of risk, which the potential failure mode holds for the system by evaluating the severity, occurrence (likelihood) and the probability of the possible causes using a relative scale of 1-10 for each index. Greater potential risk is associated with a higher RPN.

Equation 3: Calculation of risk priority number

$$RPN = Sev \times Occ \times Det$$

Source: (Kulkarni & Shrivastava, 2013)

The FMEA is a tool, which can be incorporated into a larger problem-solving system to enhance the operational capability of a company. It anticipates predefined failure modes of a process (Alexa & Kiss, 2018). The FMECA is an extension of the FMEA which includes a criticality analysis (USA DOD, 1980). A cross-functional team performs this exercise. A completed example of the FMEA is illustrated in Table 31.

2.8.1. Severity and classification

The severity ranks the impact of the failure mode on the process equipment, environment and operator. Table 22 details the severity and the associated ranking when evaluating the effects of the process failures.

The classification is assigned based on the severity of the cause to identify the process controls required. The classification used are Critical, Major A, Major B and minor which is linked to process capability (see Table 22).

The capability indices are tied to the severity of the failure mode. Table 22 contains the information used to classify the characteristics using the FMEA, which then determines the capability index. The descriptions, effect and significance to the process of each ranking are discussed (see Table 22), which is adapted from an internal procedure, literature and the author's experience in the field of process safety management (See Table 22).

Critical

A critical defect or failure is likely to result in:

- Hazardous or unsafe conditions for individuals using, maintaining or depending upon the product.
- Hazardous or unsafe conditions for the equipment used.
- the prevention of the performance of the tactical function of a major end item such as a ship, aircraft, tank, missile, space vehicle, communications system, land vehicle, surveillance system, or major part thereof.

Major A

A defect or failure that is likely to result in a failure of the unit or product for its intended purpose.

Major B

A defect or failure, other than critical or Major A, that is likely to result in the reduction of the efficiency of the unit or product for its intended purpose.

Minor

A minor defect or failure that is not likely to reduce the efficiency of the unit or product for its intended purpose, although it can have negative implications with respect to cost and schedule.

2.8.2. Occurrence

The occurrence rating ranks the frequency of the cause of the failure mode. A ranking criteria is illustrated in the table below. This is a relative ranking and not an absolute value.

Table 4: Table of relative ranking for probability of occurrence adapted from Kulkarni & Shrivastava (2013)

Rating	Probability: Occurrence	Possible failure rate
10	Very High	≥ daily
9	High	every 3 - 4 days
8	High	weekly
7	High	monthly
6	Moderately High	every 3 months
5	Moderately	every 3 - 6 months
4	Moderately Low	annual
3	Low	every 1 - 3 years
2	Low	every 3 -5 years
1	Remote	≥ 5 years

2.8.3. Detection

Detection relates the probability of detecting the cause of the failure mode to a relative ranking.

Table 5: Relative ranking for probability of detection adapted from Ford (2011)

Detection	Criteria	Detection Method	Ranking
Almost impossible	Absolute certainty	Cannot detect	10
Very remote	Controls will probably not detect	Control is achieved with indirect or random checks	9
Remote	Controls have poor chance of detection	Control is achieved with visual inspection	8
Very Low	Controls have poor chance of detection	Control is achieved with double visual inspection only	7
Low	Controls may detect	Control is achieved with charting methods such as SPC	6
Moderate	Controls may detect	Control is achieved with variable gauging after processing	5
Moderately High	Controls have good chance to detect	Error detection in subsequent operations using gauging and first-off inspection	4
High	Controls have good chance to detect	Error detection at the station by multiple layers of acceptance. Cannot accept discrepant part	3
Very High	Controls almost certain to detect	Error detection at station using automated gauging	2
Almost Certain	Controls certain to detect	Discrepant parts cannot be manufactured. Error proof product design	1

2.9. 8D Problem-solving methodology

The 8D problem-solving methodology was initially established and used by the FORD motor company, introduced in the 1980s. The methodology was then called TOPS, which is the abbreviation for team orientated problem-solving (Kumar & Adaveesh, 2017). The methodology consists of eight steps employed to eliminate problems using fact-based root cause analysis (Alexa & Kiss, 2018; Krajnc, 2012; Kumar & Adaveesh, 2017).

The steps are:

1. Establishing a team
2. Problem description
3. Immediate containment
4. Root cause analysis
5. Corrective action
6. Measuring effectiveness of corrective action
7. Expansion - preventive actions
8. Conclusion and congratulation of team members

Problem-solving forms a major part of continuous improvement as the elimination of root causes and implementation of preventive actions greatly supports the drive for continuous improvement. Problem-solving methodologies can form the basis of continuous improvement methodologies, which are further discussed in the following section.

2.10. Continuous improvement methodologies

Organisations are striving to develop sustainable business platforms by reducing business process waste via the application of continuous improvement methodologies (Kumar, Antony, Singh, Tiwari & Perry, 2006).

2.10.1. Six Sigma

Six Sigma is a formal, statistical problem-solving methodology that is implemented by defining, measuring, analysing, improving and controlling processes (Antony & Banuelas, 2002; Goh & Xie, 2003). Hallam (2010) defines Six Sigma as a tool that measures and lowers variability in processes and subsequently reduces defects. Antony & Banuelas (2002) define six sigma in business and statistical terms. From a business perspective, Six Sigma is a strategy that can improve profitability by driving out waste and improving process efficiency. From a statistical perspective Six Sigma refers to the minimisation of defects per million opportunities (DPMO) to 3.4 (see Figure 9 and Table 6). Six Sigma emphasises customer requirements, defect prevention, cycle time reduction and cost savings by eliminating non-value-adding costs (Pyzdek & Keller, 2010). Six Sigma was developed by Motorola in 1980 in a response to a demanding production plan and to minimise variability and non-conformances (Montgomery, 2009).

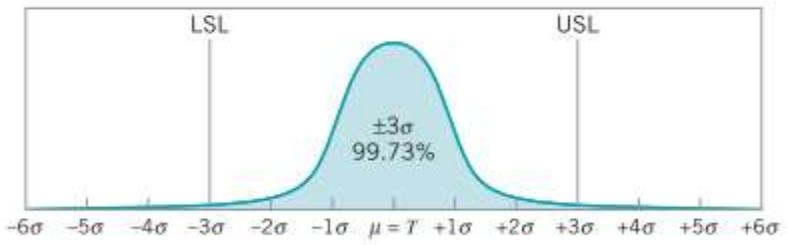


Figure 9: Normal distribution plot – Six Sigma

Table 6: Six Sigma distribution

Spec Limit	Percent Inside Specs	PPM Defective
± 1 σ	68.27	317300
± 2 σ	95.45	45500
± 3 σ	99.73	2700
± 4 σ	99.9937	63
± 5 σ	99.999943	0.57
± 6 σ	99.9999998	0.002

Source: (Montgomery, 2009)

Six Sigma is implemented using the problem-solving methodology; Define-Measure-Analyse-Improve-Control (DMAIC).

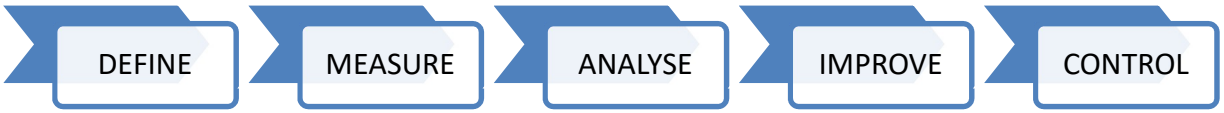


Figure 10: DMAIC process methodology

Adapted from: (Kumar *et al.*, 2006)

Define phase

To define in Six Sigma is to fully articulate the business problem according to the current situation based on customer feedback, the strategy and mission of the company. Pyzdek & Keller (2010) state to define the goals of the improvement activity.

Measure phase

Measure requires the selection of the characteristic to be investigated, process mapping, evaluating the accuracy and precision of the measuring system, collecting and recording data and evaluating the baseline

capability of the process (Antony *et al.*, 2012). The measure phase therefore establishes metrics to evaluate the defined goal.

Analyse phase

Analyse entails the identification of the root cause of the variability identified in the Define stage. Exploratory and descriptive data analysis techniques are used to aid the understanding and interpretation of the data. The aim is to identify the gap between the current process performance and how to achieve the desired process performance, validating the root cause of the variability. Tools such as hypothesis testing, cause-and-effect diagrams and failure modes and effects analysis are used (Chan *et al.*, 2014; Pyzdek & Keller, 2010).

Improve Phase

In the improve phase a solution is identified by using tools such as brainstorming and Design of Experiments (DOE). The solutions are tested and validated to ensure a permanent improvement solution is set in place for the root cause identified in the Analysis phase (Romdhane *et al.*, 2017).

Control phase

The control phase aims to sustain the gains achieved after successful improvement. This involves an updated monitoring system to ensure sustainability and continual improvement (Romdhane *et al.*, 2017).

SPC is a common tool used in Six Sigma, especially during the measure, analyse and control phases. While Six Sigma mainly focuses on improved process performance, when used in conjunction with tools such as LEAN, the potential effect increases. LEAN is a method used to reduce process waste, increasing efficiency.

2.10.2. Lean

The term 'LEAN' was coined by James Womack in his book *The Machine that changed the world* (Hallam *et al.*, 2010). Effectively Lean is a combination of different tools focused on maximum employee involvement. The foundation of Lean manufacturing was pioneered by then Vice President of Toyota, Taichi Ohno (Hallam *et al.*, 2010; Sugimori, Kusunoki, Cho & Uchikawa, 1977), who developed the Toyota Production System (TPS). The TPS is defined by 'Just in Time' manufacturing and the idea of utilising the ultimate capability of each employee. This entails employing a strategy which utilises a set of proven tools and techniques with the aim to reduce lead times, inventories, set up and change over times , equipment downtime, scrap, rework and other wastes of the hidden factory (Kumar *et al.*, 2006).

The Toyota production system is an excellent example of how specific tools were utilised to manufacture premium products at a competitive cost. The system was established to compensate for the lack of natural

resources when compared to North American and European counterparts (Hallam *et al.*, 2010; Sugimori *et al.*, 1977). Given Japan's situation, they were forced to ensure products are manufactured in the cheapest possible manner in order to compensate for elevated imported raw material prices. The TPS is driven by cost reduction through the reduction of waste, thereby ensuring application of maximum effort to attain low-cost production (Hallam *et al.*, 2010; Sugimori *et al.*, 1977). This involves a system that eliminates waste by utilising the minimum amount of equipment, materials, labour and time (Hallam *et al.*, 2010; Sugimori *et al.*, 1977). The full utilisation of all and any employee is fundamental. The TPS system focuses on ensuring that employees are working at full capacity and at the peak of their capabilities, the concern was not with idle time on machines, but idle time on employees. This led to the origin of JIT – Just in Time manufacturing.

Womack and Jones (1997) defined TPS by means of the following objectives:

- Precisely specify value relative to the specific product
- Identify the value stream of each product
- Make value flow without interruptions
- Let the customer pull value from the producer and pursue perfection

Continuous improvement and Quality have become synonymous with the most recent versions of QMS based on a risk-based approach and continuous improvement. A favourable market position is dependent on various principles; however, a certified QMS is imperative to attaining a lucrative market share.

2.11. Quality management systems and ISO 9001:2015

The International Organization of Standardization (ISO) developed a guideline which all accredited management systems must adhere to (ISO, 2015). Accordingly, the "adoption of a quality management system is a strategic decision of an organization that can help improve its overall performance and provide a sound basis for sustainable development initiatives" (ISO, 2015). The first standards were issued in 1987 (Montgomery, 2009). By implementing a quality management system corresponding to the ISO 9001:2015 guidelines, a company may:

a) Develop the ability to consistently produce quality products
b) Create an environment where continuous customer satisfaction can be enhanced
c) Address risk and opportunities in line with company objectives and the scope of the quality management system
d) Nurture the ability to conform to the ISO requirements

The guidelines employ a risk-based approach and utilise the Plan-Do-Check-Act (PDCA) (Shewart - Figure 11) cycle to implement the system. This allows for continuous improvement and enhanced customer satisfaction.

PDCA – Plan Do Check Act

The Shewart cycle (Figure 11) ,was proposed by Deming as a guideline to continuous improvement (Montgomery, 2009). The cycle is sometimes used as Plan-Do-Study-Act (PDSA). The process is used as an iterative approach to problem solving and continuous improvement and strives for permanent positive change in a process. This approach has been adopted by various guidelines and frameworks with the most notable being the ISO 9001:2015.

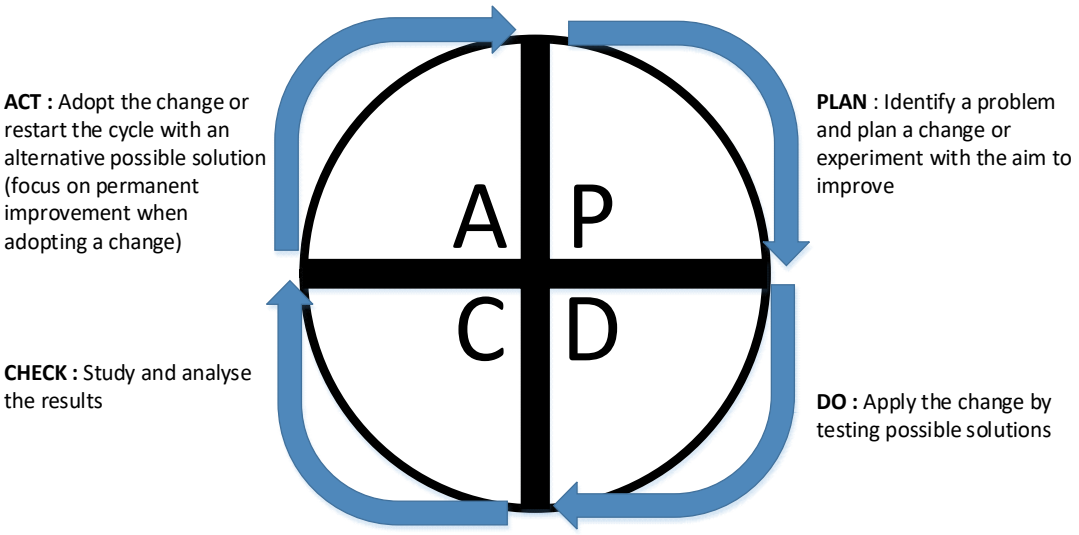


Figure 11: PDCA cycle - Developed by Deming and Shewart

Adapted from (Montgomery, 2009)

ISO 9001:2015 is divided into 10 clauses. If accredited by ISO (2015), the QMS of a company shall adhere to these clauses. These clauses detail how a quality management system should be defined and are listed as:

1. Scope
2. Normative References
3. Terms and Conditions
4. Context of Organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

The individual clauses are divided into subsections. A quality management manual is generated specific to a company's quality management strategy and elaborates on the compliance or the strategy that will ensure adherence to the ISO Standard. The company will generate policies and procedures that detail the approach on how to address day-to-day and strategic matters. The QMS is audited on a three-yearly basis by an

external third-party auditing firm, which then recommends the certification of a specific company's QMS (ISO, 2015). The QMS allows for a competitive market orientation as assurance is granted to possible clients with the certified QMS. Manufacturing defect-free product, first-time right is synonymous with a successfully implemented quality management system (Besseris, 2013; Lobont *et al.*, 2011).

The implementation of a QMS requires the specific definition and differentiation of all quality-related activities in an enterprise. The function of quality management is generally divided into quality assurance and quality control.

2.12. Quality assurance

Montgomery (2009) defines quality assurance as a series of actions proactively undertaken by a company to ensure a standardised quality of products and services. Quality assurance systems enhance customer confidence as they provide credibility that the processes are capable and suitable to manufacture according to the requirement (Yunus *et al.*, 2016). In summary, quality assurance involves planned, systematic and strategic activities that provide sufficient evidence that a standardised product or service will be produced.

2.13. Quality control

Quality control encapsulates all the operational techniques and activities utilised by a company to ensure a conforming final product (Pyzdek & Keller, 2010). This involves the process of examination of products or material with the aim of identifying defective material prior to client delivery (Yunus *et al.*, 2016). Referring back to Figure 11, the PDCA cycle is employed in quality control (see Figure 12) as product validation can be performed according to the this process (Yunus *et al.*, 2016).

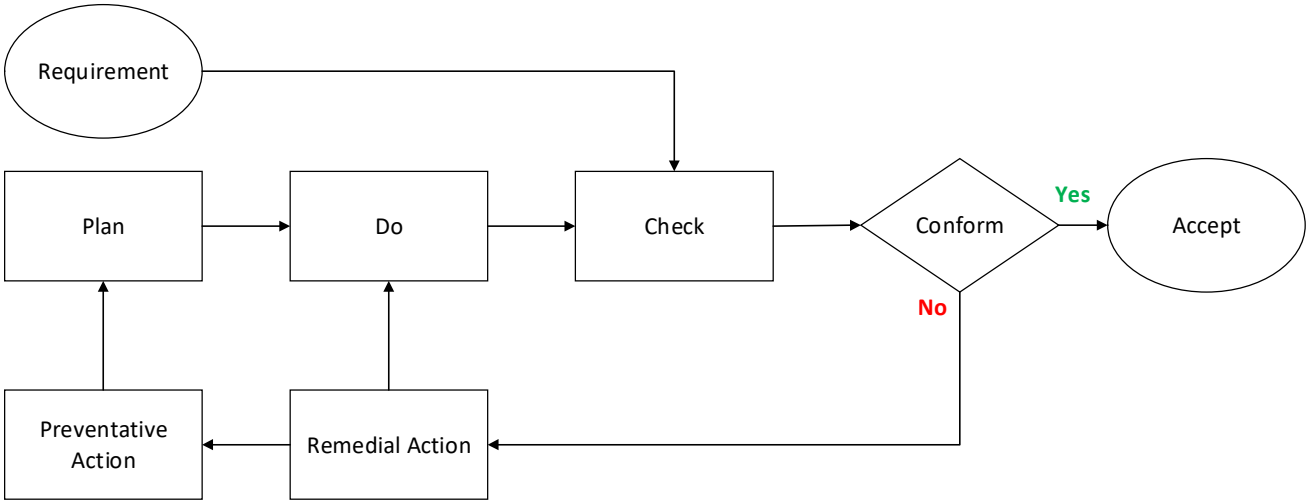


Figure 12: Quality control process flow based on PDCA

Adapted From : (Yunus *et al.*, 2016)

Continuous improvement (CI) initiatives, with the aim on quality improvement have been utilised by corporations since the 1900s. CIs were coined by larger corporations (General Electric & Motorola) in specific industries, which may restrict the flexibility and suitability for different industries of different sizes. This research study is aimed at smaller corporations with restricted resources at hand where the research product, a framework, will be validated as a case study. The following section will provide a detailed overview on how to classify an organisation using its size (employee population) and annual turnover and also elaborate on frameworks.

2.14. Industry classification, frameworks and case studies

The following section aims to define the industries based on their size. Frameworks and case studies are discussed as these aspects are critical concepts in the research study.

2.14.1. Industry classification

Small and medium-sized enterprises contribute greatly to the economic growth of developed and developing countries (Sharma & Kharub, 2014b). SMEs are constrained with resources and contest with large operational entities. They, however, possess flexibility, agility, versatility and are less bureaucratic institutions, which allows them to effectively adapt to the demands of the market (Yusof & Aspinwall, 2000). It is essential for these enterprises to ensure the reliability and sustainability of their production processes while managing the challenges of limited capital investment, finances and professional talent (Antony & Bhattacharyya, 2010; Yusof & Aspinwall, 2000). Literature lacks detailed guidelines on continuous improvement initiatives and business excellence strategies for this sector and given the criticality of their contributions to their respected economies, it is imperative to develop holistic approaches which are conducive for business excellence and which fit their company profiles (Antony & Bhattacharyya, 2010; Sharma & Kharub, 2014b).

Table 7 illustrates the requirements as stated by the DTI (1996) for companies to be classified in the SME bracket. The study specifically focuses on the total full time equivalent employees as a benchmark and as the limiting resource for CI initiatives.

Table 7: Classification of SMEs as stated by the National Small Business Act 102 of 1996

Sector or Subsectors In Accordance With The Standard Industrial Classification	Size or Class	Total Full-Time Equivalent of Paid Employees	Total Annual Turnover In ZAR	Total Gross Asset Value In ZAR (Fixed Property Excluded)
		Less Than:	Less Than:	Less Than:
Agriculture	Medium	100	4000000	4000000
	Small	50	2000000	2000000
	Very Small	10	400000	400000
Mining and Quarrying	Medium	200	30000000	18000000
	Small	50	7500000	4500000
	Very Small	20	3000000	1800000
Manufacturing	Medium	200	40000000	15000000
	Small	50	10000000	3750000
	Very Small	20	4000000	1500000
Electricity, Gas and Water	Medium	200	40000000	15000000
	Small	50	10000000	3750000
	Very Small	20	4000000	1500000
Construction	Medium	200	20000000	4000000
	Small	50	5000000	1000000
	Very Small	20	2000000	400000
Retail and Motor Trade and Repair Services	Medium	100	30000000	5000000
	Small	50	15000000	2500000
	Very Small	10	3000000	500000
Wholesale Trade, Commercial Agents and Allied Services	Medium	100	50000000	8000000
	Small	50	25000000	4000000
	Very Small	10	5000000	500000
Catering , Accommodation and other Trade	Medium	100	10000000	2000000
	Small	50	5000000	1000000
	Very Small	10	1000000	200000
Transport, Storage and Communications	Medium	100	20000000	5000000
	Small	50	10000000	2500000
	Very Small	10	2000000	500000
Finance and Business Services	Medium	100	20000000	4000000
	Small	50	10000000	2000000
	Very Small	10	2000000	400000
Community, Social and Personal Services	Medium	100	10000000	5000000
	Small	50	5000000	2500000
	Very Small	10	1000000	500000

Source: (DTI, 1996)

The proposed framework will be developed for an SME. Given this, the following section will define a framework.

2.14.2. Frameworks

Jabareen (2009) defines a framework as a network of interlinked concepts which collectively provides a comprehensive understanding of a subject. A conceptual framework provides an interpretative approach to a reality by evaluating concepts and quantifying their presence and occurrence (Jabareen, 2009). Rather than

offering a theoretical explanation about a concept, a framework provides understanding of the phenomena. Miles and Huberman (1994) states that a conceptual framework "lays out the key factors, constructs, or variables, and presumes relationships among them". Therefore, a framework be will developed to guide and enhance the understanding of SPC and its implementation.

The framework will be evaluated as a case study in a setting where the environment is classified as a South African SME, based on the number of employees and annual turnover.

2.14.3. The case study

A case study involves the detailed and in-depth analysis of a specific case or cases (Bryman, Bell, Hirschsohn, dos Santos, du Toit & Masenge, 2014). Case researchers focus on the detailed analysis and investigation of a specific setting or context specific to a geographical location such as a workplace or organisation (Bryman *et al.*, 2014). The company under investigation specialises in the development and manufacturing of chemical materials.

With the focus on SMEs and their constraints, the following section reviews published implementation frameworks for SPC, and seeks to identify deficiencies, critical success factors and opportunities for improvement.

2.15. Review of published implementation frameworks

"*Implementing SPC does not improve quality. SPC is a tool to help people improve quality*" (Carter, 1993).

The desire to implement SPC is driven by proactiveness as the reactiveness of an inspection-based quality control system is unreliable, costly and time-consuming (Mason & Antony, 2000). The SPC initiative is commonly avoided due to the lack of awareness of the potential benefits (Mason & Antony, 2000). The project commonly fails due to an unclear purpose and an ill-constructed implementation plan (Sharma & Kharub, 2014a). Therefore, a requirement exists to formulate an implementation framework for SPC with the aim to assist SMEs in South Africa. Frameworks and guidelines on SPC can be found in literature, however these frameworks lack detailed methodologies on how to plan for SPC and deploy SPC. There is a need to evaluate existing published frameworks on their strengths and deficiencies with regards to implementation guidance and support.

The frameworks focused on are sourced from various continuous improvement initiatives. The lack of statistical methods in LEAN led to the omission of implementation frameworks from this domain as it will not add value to this study. However, it is worthy to mention the value that the LEAN initiative can add to a business as mentioned in Section 2.10.2. The reviewed frameworks were analysed for CSFs, strengths and

weaknesses as identified by the author. The review provided a platform to develop the deployment framework for the implementation of SPC in SMEs.

The following section contains a summary of 16 reviewed frameworks and highlights the strengths and weaknesses of each individual framework. The 16 published frameworks were selected as the result of a systematic and a random literature review, which is explained in detail in Chapter 3.

The articles reviewed were from a broad variety of industries and countries. The following chapter discusses an empirical analysis performed on the reviewed articles, providing an overview on the research already performed on SPC and statistical methods in manufacturing.

2.15.1. Empirical analysis of articles

Table 8 contains descriptive information of the reviewed articles, also indicating the industry from which the initiative originated. Of the 16 articles four originate from a mechanical environment where four are academic research studies in continuous improvement and five publications are relevant to the electrical and electronic domain. The sourcing of articles for the empirical analysis are discussed in section 3.2.

Table 8: Empirical information on screened articles

No.	Title	Reference	Year Published	Country	Industry
1	Statistical Process Control for total Quality	(Ali, 1992)	1992	USA	Fabrication of Parts
2	Effective Implementation of SPC in Wide Area Manufacturing Systems	(Carter, 1993)	1993	USA	Electronic
3	Doing it Right Second Time	(Kumar & Motwani, 1996)	1996	USA	Electronic
4	Implementing SPC in a small organisation: a TQM approach	(Krumwiede & Sheu, 1996)	1996	USA	Electronic
5	SPC Implementation for Improving Product Quality	(Donnell & Singhal, 1996)	1996	USA	Electrical
6	A Framework for Implementation of Statistical Process Control	(Does, Trip & Schippers, 1997)	1997	Netherlands	Electronic
7	A conceptual framework for TQM implementation for SMEs	(Yusof & Aspinwall, 2000)	2000	UK	Academic
8	A conceptual framework for the effective implementation of statistical process control	(Antony & Taner, 2003)	2003	UK	Academic
9	The Use of SPC Tools for preliminary assessment of an aero engines maintenance process and prioritisation of aero engines faults	(Vassilakis & Besseris, 2010)	2010	UK	Aero Engines

No.	Title	Reference	Year Published	Country	Industry
10	Effective implementation of statistical process control	(Noskievičová, 2010)	2010	Czech Republic	Automotive
11	Six Sigma implementation framework for SMEs – a roadmap to manage and sustain change	(Kumar *et al.*, 2011)	2011	UK	Academic
12	Implementation of SPC Techniques in Automotive Industry: A Case Study:	(Prajapati, 2012)	2012	India	Automotive
13	Quality Improvement Using Statistical Process Control Tools in Glass Bottling Manufacturing Company	(Awaj, Singh & Amedie, 2013)	2013	Ethiopia	Glass Manufacturing
14	A Case of implementing SPC in a pulp mill	(Rantamäki et al., 2013)	2014	Finland	Pulp Mill
15	Attaining competitive positioning though SPC – an experimental investigation from SME	(Sharma & Kharub, 2014b)	2014	UK	Academic
16	Success factors in the implementation of statistical process control: Action research in a chemical plant	(Toledo et al., 2017)	2017	Brazil	Chemical Process

Figure 13 and Figure 14 illustrate the publishing period and location distribution of the reviewed articles. The highest number of articles focusing on the implementation of SPC with a clear guideline or framework presented, was published in 1996 with UK and USA as the countries with the most publications. As articles were consistently published over the years up until 2017; a worthy observation is that the consistent output of articles related to this domain indicates an existing gap in literature related to SPC implementation.

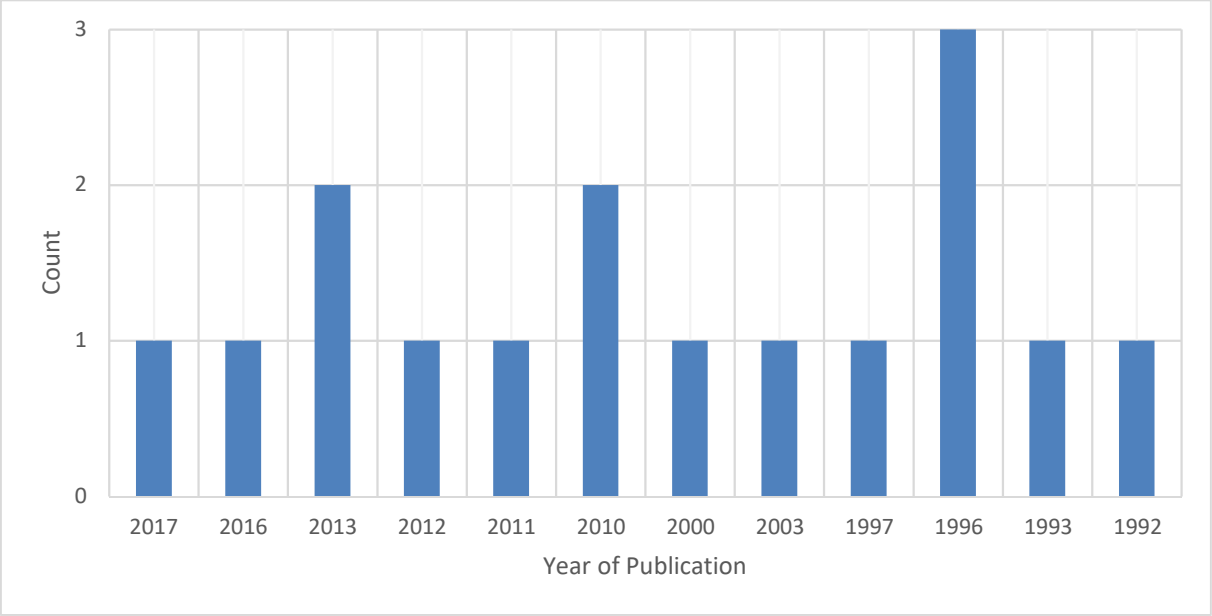


Figure 13: Distribution plot of publication year of articles related to the implementation of SPC

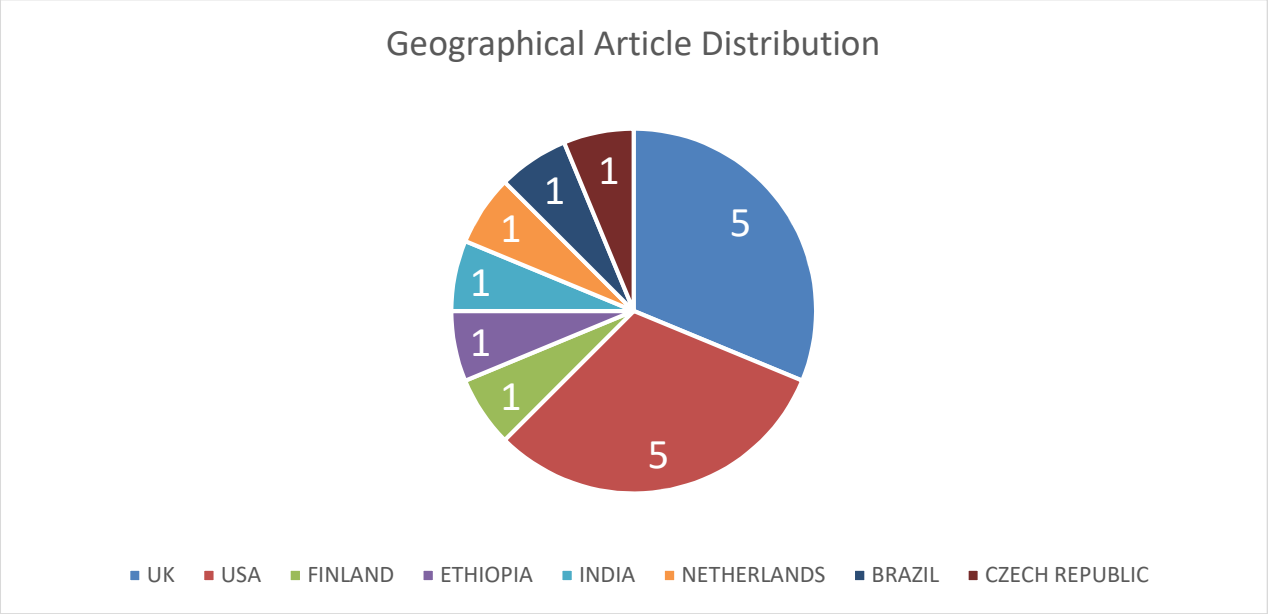


Figure 14: Countries referred to in the identified SPC publications

2.15.2. Review of implementation frameworks

2.15.2.1. Statistical process control for total quality (Ali, 1992)

Ali (1992) provides a comprehensive reasoning, with the focus on the role of SPC in TQM. The author presents his definition of a process, variation, SPC, control charts and then ultimately runs through the implementation of SPC and the CSFs. As SPC is used to reduce process variability, Ali (1992) emphasises the naturally low probability of repeatability with any process or manufactured object. Naturally this supports the requirement for the control and reduction of variability in order to consistently manufacture compliant products.

Ali (1992) defines the goals of SPC as:

- The reduction of variation
- Simplification of procedures, methods and tools
- Sustained performance
- Maximising current equipment efficiency
- Information for better cost estimation

The paper further covers the construction and calculation of the parameters and limits of a control chart with the available data. The implementation of SPC follows a four-phase implementation checklist.

Phase One

The first phase of the implementation pertains to the definition of the plan. This involves:

- Project planning
- Responsibilities
- Scheduling

The planning demands urgent completion to ensure awareness, resource commitment and the establishment of the team and delegation responsibilities.

Phase Two

The second phase requires the collection and processing of historical data. This entails:

- Data collection
- Review of historical data (process and product)
- Review of equipment performance records
- Review of fabrication procedures
- Process capability study

This phase provides the platform and baseline for the SPC study. The process performance will be measured against this baseline.

Phase Three

The third phase focuses on developing an effective and efficient plan with the aim to collect, record and process essential data of the processes. Based on this, a feedback controlled corrective action system is set in place to identify and minimise variation. This is done by ensuring:

- Effective sampling
- Effective data collection (ties in with sampling)
- Preparation of control charts
- Initiation of feedback control system with SPC and corrective actions
- Document changes

Phase Four

The fourth phase of the implementation checklist focuses on sustained continuous improvement. The focus is ensuring that the system is properly implemented and maintained by following the below mentioned steps:

- Companywide implementation
- Monitoring effectiveness for continuous improvement
- Continuous process auditing
- Maintain the SPC record

A key factor to sustained success is to ensure that the process is properly documented and the appropriate documentation changes enforced.

Ali (1992) emphasises the application of technical expertise during earlier stages of the manufacturing process to ensure a reduced variability and a consistent output criteria.

2.15.2.2. Effective implementation of SPC in wide area manufacturing systems (Carter, 1993)

Carter (1993) identified two specific components which are critical for the successful implementation of SPC. The implementation guideline focuses on the criticality of important software systems and an organisational model for success. The organisational model for success is a seven-component responsibility framework with education as the focal point. The roles, responsibilities and types of training are specified and explained starting with the manufacturing executive up until the operator. The seven interlinked concepts are illustrated in Figure 15.

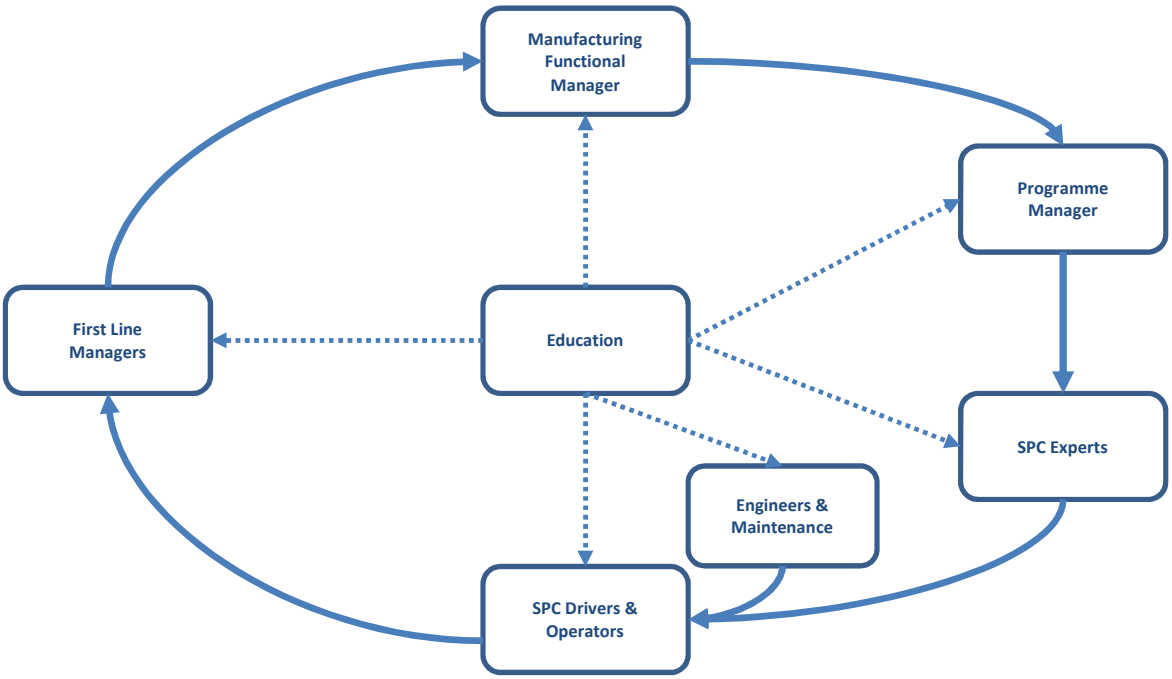


Figure 15: Organisational structure for SPC programme implementation

Source: (Carter, 1993)

The implementation is governed by the responsibility of each character:

- Manufacturing executive – enforce management commitment and fully support the programme.
- Programme manager – overall responsibility for SPC implementation.
- First line managers – coordinate implementation in their area and take part in team meetings.
- Engineers and maintenance – technical support and documentation.
- SPC experts – trained operators facilitate and lead implementation, construct control charts and are responsible for the out-of-control action plan.
- SPC drivers and operators – responsible for daily monitoring, handover and dealing with out-of-control points.

In addition, the paper focuses on a detailed computer-based software system which automatically links up with the machines and equipment to collect, process and display data to operators and management. The

system identifies the out-of-control point and contains the capability to stop upon identification, but the problem-solving aspect is up to the user of the system to administer and enforce.

Carter (1993) conveys SPC as control charts, this emphasises the author's stance that SPC is the tool used to identify the problem. The author stresses the importance of having a parallel implemented problem-solving methodology to enhance the probability of success of the application of statistics in a process environment.

2.15.2.3. Doing it right the second time (Kumar & Motwani, 1996)

Kumar and Motwani (1996) describe their 16-step programme used to implement SPC at Laser Inc. The SPC programme was pursued in order to assure a high quality product coupled with an efficient process as 100% inspection was not a viable option. The programme was implemented on two occasions with an unsuccessful initial attempt. The failed implementation was as a result of incapable processes, ill planning, lack of management commitment and the lack of understanding of the SPC philosophy. The 16-step implementation plan is supported by a control chart selection procedure and an out-of-control reaction plan. The 16 steps are:

1. Establish an implementation team.
2. Training and educating of top management on SPC.
3. Select product for SPC implementation.
4. Define and document customer requirements and expectations.
5. Generate process flow chart and documentation.
6. Create SPC plan.
7. Present to management for approval.
8. Train operators.
9. Implement SPC on key operations and collect and chart initial data.
10. Compute control charts.
11. Review for out-of-control points.
12. Determine assignable causes.
13. Calculate process capability.
14. Determine acceptability of capability.
15. Problem-solving activities.
16. Run control plan.

The organisation, according to the authors, believes that their implementation plan is sufficiently comprehensive, which makes it applicable in any industry. SPC provides operators with a platform to make data-driven decisions. The processes were stabilised and became predictable and consistent. Furthermore, SPC provides a common language between management and operators and has also established a platform for continuous improvement.

2.15.2.4. Implementing SPC in a small organisation: A TQM approach (Krumwiede & Sheu, 1996)

Krumwiede and Sheu (1996) deliberate the importance of a SPC programme in a TQM system. The authors split the TQM philosophy into a management system and a technical system. The management system relates to the strategising and utilisation of human resource processes to dictate their influence on product and service quality. The technical system relates to the quality assurance of planning, design, development and manufacturing processes. The authors specifically highlight the dependence of these two systems on each other by relating the success of SPC, which forms part of the technical management system to management support, employee involvement and teamwork.

The drive for the study is supported by two objectives. The first is the six-step implementation procedure (Figure 16) which assists SMEs with the implementation of the CI initiative and secondly, to exhibit the benefits SPC holds for small companies and batch processes.

The first step in the implementation process is to obtain management commitment. This is done to ensure companywide buy-in and allows for the establishment of a platform to integrate SPC into the daily operational activities, preventing any operational disruptions. The second step is the appointment of the SPC leader. This person will lead the integration and deployment of SPC. The third step is the selection of a pilot study plant. The pilot study creates a platform on which knowledge can be developed. Furthermore, the pilot study demonstrates early success with the programme by influencing those with negative perceptions of it. The fourth step is the formulation of manufacturing documentation and procedures for the manufacturing line. This provides a platform for the unveiling of SPC. The fifth and sixth steps involve the training of employees followed by the collection of data and the construction of control charts.

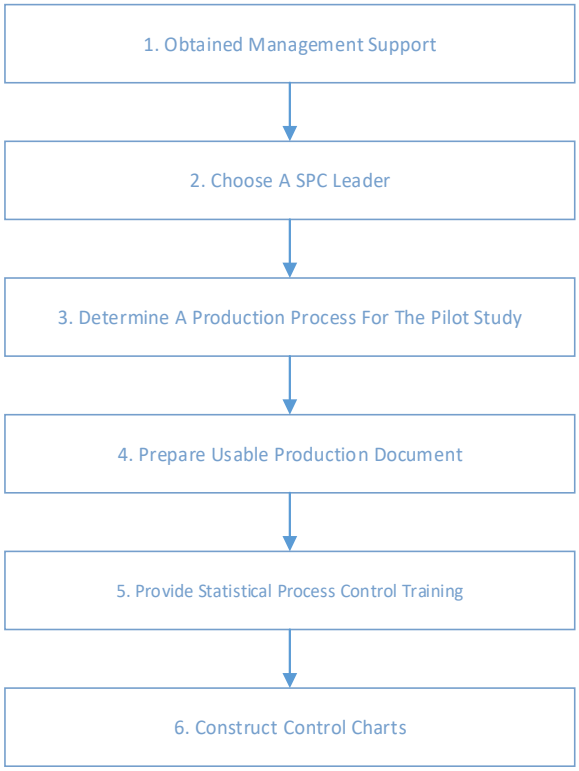


Figure 16: Proposed SPC Implementation Procedure

Source: (Krumwiede & Sheu, 1996)

The authors allude to SPC as a communication tool between operators and supervisors while continuously promoting CI initiatives and total quality.

2.15.2.5. SPC implementation for improving product quality (Donnell & Singhal, 1996)

Donnell and Singhal (1996) deliberate the SPC Implementation plan established by Lucent Technologies (formerly known as AT & T Power Systems). The article highlights key requirements to develop a prize-winning total quality management system, which includes a SPC programme as the company won the Deming Prize in 1994. The authors argue that a well-documented and structured SPC programme, employee training, teamwork and senior management commitment are key requirements for a successful SPC programme. The implementation plan is divided into an initial and ongoing set of activities (Table 9).

Table 9: Implementation detail (Donnell & Singhal, 1996)

Initial Activities	Ongoing Activities	Implementation Approach
Identify key processes Determine the process quality of each key process Identify critical control points Select control charts Develop a quality control process chart Provide training Process control	Process quality Process control Process improvement	Quality council SPC lead team SPC user groups Quality improvement teams

Initial activities

The paper presents a set of initial activities formulated to guide the initiation process. This is done by offering insight into the identification of key processes and metrics. Furthermore, the paper discusses training and initial process control activities which are classified as essential to the success of SPC.

Ongoing activities

Ongoing activities detail the initiation of monitoring, control and improvement after the initial activities. The section focuses on process quality, process control and process improvement using data and statistics.

Implementation approach

The implementation approach details the teams involved with the start, implementation and maintenance of the SPC programme. This section provides the responsibility matrix and highlights the overall approach towards quality improvement as displayed in Figure 17. Donnell and Singhal (2003) report on the involvement of the chief operating officer, which directs the SPC programme with a trickle-down approach towards the operators, who collect the data and with support from the quality engineering team, act accordingly to eliminate special cause variation.

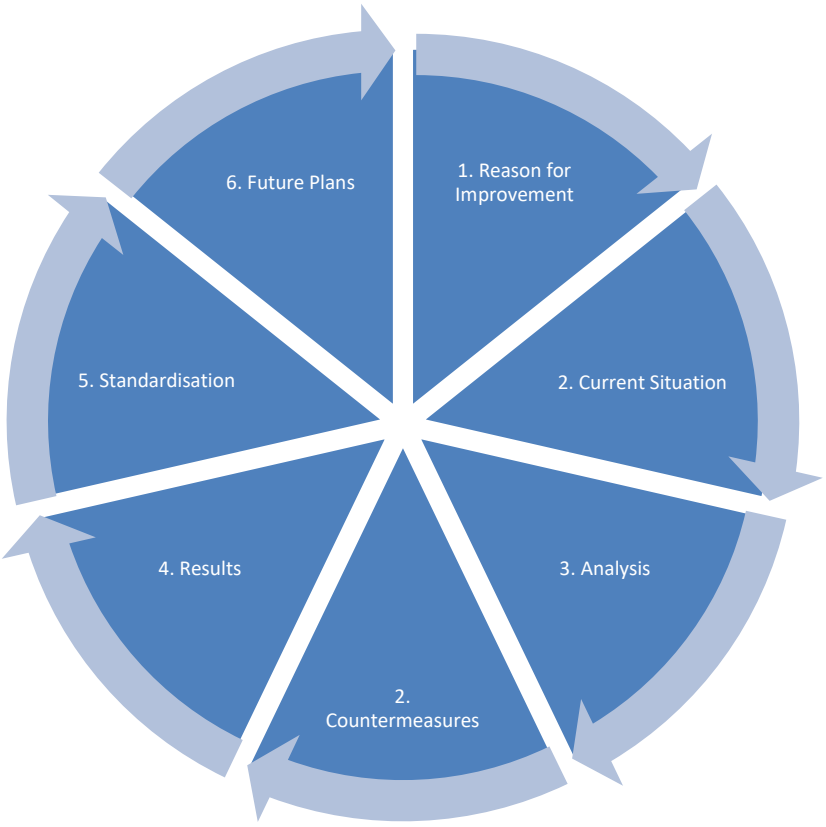


Figure 17: Quality improvement story for quality improvement teams

Adapted from: (Donnell & Singhal, 1996)

2.15.2.6. A framework for implementation of statistical process control – (Does *et al.*, 1997)

Does, Schippers and Trip (1997) highlight the hands-on approach presented in their framework. The framework sets out how to analyse, improve and monitor a process by applying statistical thinking. Their framework employs both organisational and methodological aspects. Company-wide implementation with the aim to set the stage for the implementation of TQM forms the core of the approach. The author emphasises the delegation of tasks, responsibilities and authority to the lowest possible level. Top management commitment is highlighted as the key factor. Once top management commitment has been achieved the organisational implementation approach is broken down into four phases namely:

- Awareness
- Pilot projects
- Integral implementation in production
- Total quality

The methodological implementation is based on a step-by-step procedure on how to implement SPC in an organisation and follows the steps of:

1. Process description
2. Cause and effect analysis

3. Risk analysis
4. Improvements
5. Define measurements
6. R & R study
7. Control charts
8. OCAP – Out-of-control action plan
9. Process capability study
10. Certification

The fundamental purpose of the framework is the development of a foundation for TQM. The framework has been implemented in both high volume and complex low volume manufacturing environments.

2.15.2.7. A conceptual framework for TQM Implementation for SMEs (Yusof & Aspinwall, 2000)

Yusof and Aspinwall (2000) proposed a framework focusing on three key elements to aid in the gradual progression and selection of quality tools and initiatives to support SMEs to implement and maintain continuous improvement in the organisation. The structure of the implementation framework provides a platform for initiatives to become permanent elements of the day-to-day operations.

The proposed framework consists of a quality toolbox (Figure 18), a general implementation methodology and activities required to review and improve the implemented processes, all driven by a coordinating body. By including the general methodology in their framework, Yusof and Aspinwall (2000) include a roadmap for implementation detailing six basics steps to follow for each initiative. Implementing the system bit by bit allows for a single initiative to be standardised before moving into the next initiative, thereby assisting the enterprise in adapting to a continuous improvement environment by establishing a foundation to successfully support the development of other initiatives with the same intention. The framework is grounded on the principle of individual progression for each initiative, passing through all six steps of the general methodology before moving on to the next.

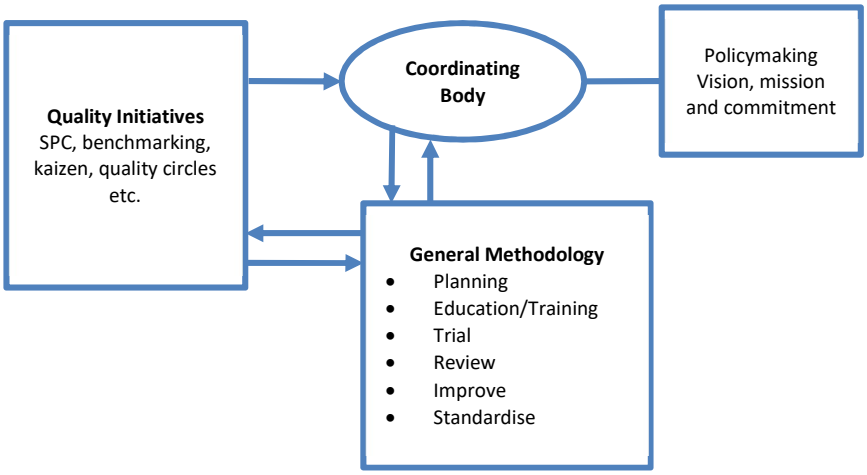


Figure 18: TQM conceptual framework of Yusof and Aspinwall (2000)

The authors believe that quality and continuous improvement initiatives require alteration in order to fit the blueprint of SMEs and cannot be directly transferred from larger enterprises to SMEs. Regardless of the constraints on SMEs, their flexibility, agility and versatile human resource pool allow for quick adaption to new techniques as well as direct task driven implementation.

2.15.2.8. A conceptual framework for the effective implementation of statistical process control (Antony & Taner, 2003)

Antony and Taner (2003) reviewed four articles authored by Oakland (2008), Watson (1998), Kumar and Motwani (1996) and Does, Schippers and Trip (1997). According to Antony and Taner (2003), the engineering community is educated on the statistical and technical aspects of SPC, but lacks understanding with regards to the management and implementation of an SPC programme.

Barriers were identified such as resistance to change, which the authors categorise as technical resistance, political resistance, individual resistance and organisational resistance (Eckes, 2002). The following aspects are highlighted by the authors as factors which may hinder the deployment of SPC:

- Lack of top management commitment.
- Lack of training in SPC.
- Incorrect control chart interpretation.
- Inadequate identification process of the critical control parameter.
- Incapable measurement system.

The developed framework addresses the limitations of the four reviewed frameworks by acknowledging management issues, engineering skills, teamwork skills and statistical skills as critical success factors for the implementation of SPC (Antony & Taner, 2003). Figure 19 illustrates the proposed framework of Antony and Taner (2003).

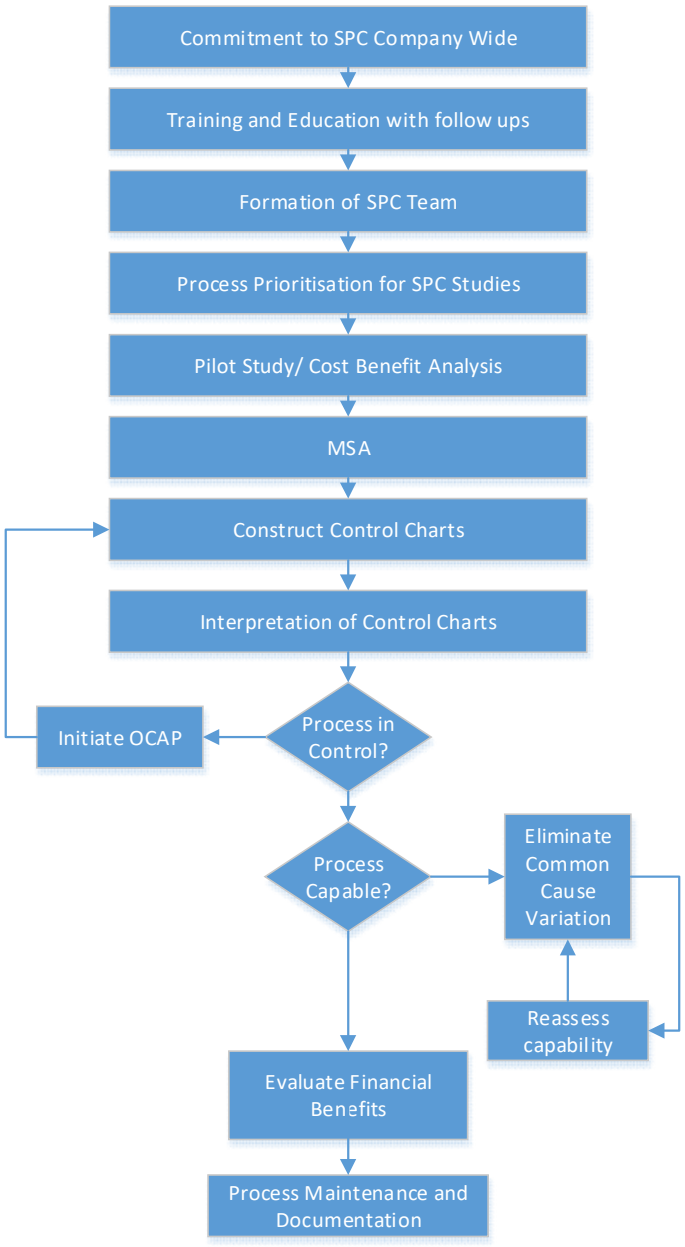


Figure 19: Conceptual framework for the implementation of SPC

Source: (Antony & Taner, 2003)

The interpretation and construction of control charts is accentuated with the discussion of the out-of-control criteria and an out-of-control action plan. Furthermore, emphasis is placed on the selection of the appropriate control chart similar to Figure 7. It is worthy to mention that Oakland (2008) promotes the use of Pareto analysis to prioritise processes for the implementation of SPC.

2.15.2.9. The use of SPC Tools for preliminary assessment of an aero engines maintenance process and prioritisation of aero engines faults (Vassilakis & Besseris, 2010)

The paper aims to provide a simplistic guideline to implement SPC, coupled with the inception of a problem-solving culture at a maintenance workshop for aero engines. In order to apply the SPC technique, the repaired

and overhauled engines were seen as products of the maintenance workshops. The data collected for the application of SPC was based on the test data of the repaired and overhauled engines. The SPC initiative was implemented using the simple methodology as illustrated in Figure 20 .

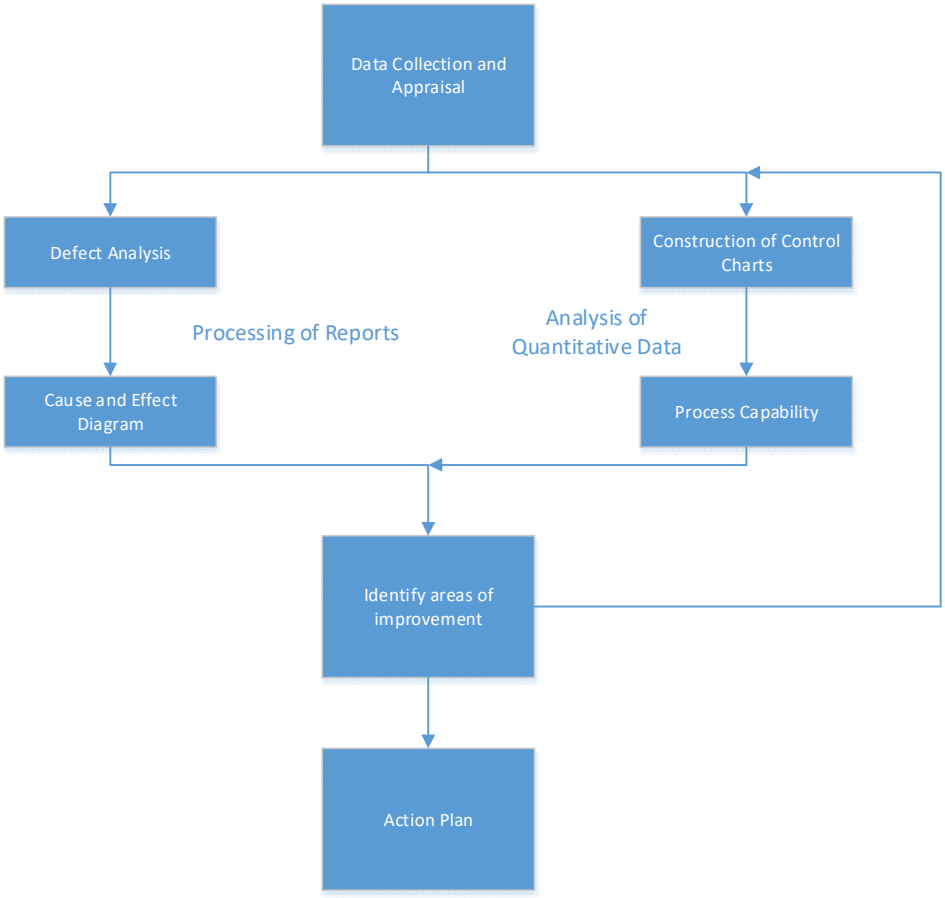


Figure 20: SPC implementation procedure by Vassilakis and Besseris

Adapted From: (Vassilakis & Besseris, 2010)

The SPC programme was implemented using the following steps:

1. Data collection and appraisal.
2. Processing of reports: ABC (Categorise from most to least critical) analysis and cause and effect diagram.
3. Numerical data analysis: control charts - capability analyses.
4. Identification of areas needed for improvement.
5. Action plan.

As mentioned earlier, the engine hauled in for repair or overhaul was seen as a product and the quality inspection was the pass or fail at the test facility. The Pareto chart was utilised to assess the frequency of the defects, subsequently the most problematic areas which required further attention were identified. The

problematic areas were then evaluated via a cause and effect diagram from which actions were derived in order to install a corrective and preventive action for the source of the problems. This cause and effect diagram was used as a roadmap to aid in the elimination of any assignable cause variation once detected at the testing area. The process is monitored using control charts to assess the statistical stability and capability of the process. A simplistic layout of the methodology is:

1. Data analysis – ABC, Pareto analysis and cause and effect diagram
2. Eliminate root case
3. Capability study
4. Control charts

Vassilakis and Besseris (2010) argue that the SPC tools implemented transcended measuring the capability of their processes, but motivated the collection of data to expand this exercise to other departments in their organisation.

2.15.2.10. Effective implementation of statistical process control (Noskievičová, 2010)

Noskievičová (2010) attempts to address the lack of problem-solving methodologies offered in existing publications by proposing a framework with subprocesses focused on problem-solving, dataset classification and control chart selection. The author proposes an expert system for problem-solving of processes in SPC. The author specifically details data verification tools, control chart selection tools and problem-solving.

The framework has a very specific focus on preparation for the SPC programme by developing a response methodology based on process inputs and process dynamics to ensure the most suitable and most proactive approach to problem-solving. The framework contains a thorough summary of actions and concepts for the different phases such as:

- Preparation of SPC implementation
- Control chart construction
- Data collection
- Computation and record of statistics into control charts and control chart interpretation
- Assignable causes identification
- Selection of action for improvement
- Realisation of action for improvement

Each section contain factors required to fulfil the specific step. However, no detail is provided on how to execute the factors. The framework lacks detail on MSA, training and education and process prioritisation. Given this, the conclusion can be made that the framework is suitable for organisations with a working SPC programme who desire to proceed to the next level by coupling the programme with a complex and detailed approach to problem-solving.

2.15.2.11. Six Sigma implementation framework for SMEs – a roadmap to manage and sustain change (Kumar *et al.*, 2011)

The research of Kumar et al (2011) aims to develop a Six Sigma framework for SMEs in order to nurture the resilience of these organisations and aid them in surviving the inconsistent and ever-changing global market.

Kumar et al (2011) highlight the importance of a step-by-step guideline to assist with the successful implementation of quality initiatives in SMEs and the significance of employee empowerment. The authors proposed the implementation of a five-phase implementation framework.

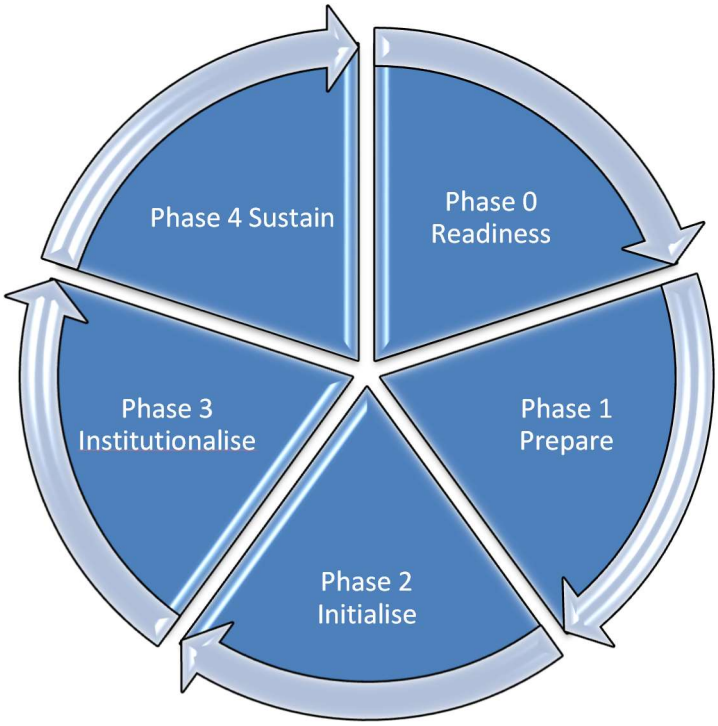


Figure 21: Five-phase framework for Six Sigma implementation

Adapted from : (Kumar *et al.*, 2011)

The five-phase implementation framework is broken down into a 12-step deployment guideline. The authors claim to have developed the 12-step plan specific for SMEs and their constraints. The framework was validated by means of a case study with feedback obtained by conducting semi-structured interviews with middle management. The framework is initiated by evaluating the readiness of an organisation. This requires an assessment of the degree of readiness against principles required for the establishment of Six Sigma. The framework focuses on:

- Leadership
- Customer focus
- Measurement and process
- Systems and control

- People management

Once confirmed that the organisation is indeed ready for the implementation of Six Sigma, the 12-step process is initiated.

1. Recognise the need for change.
2. Strong leadership and top management commitment.
3. Education and training at the senior management level.
4. Identify and train the best people for the first wave of six sigma.
5. Identify the core business processes.
6. Selecting six sigma pilot project.
7. Communicating the initial success.
8. Organisation-wide training.
9. Establish methods for evaluating processes.
10. Commitment to continuous improvement.
11. Linking Six Sigma to intrinsic motivation of employees.
12. Progression towards learning organisation.

The framework is grounded on leadership commitment and communication. The twelve-step process is proposed as a problem-solving approach and a gateway to business excellence with the aim to aid SMEs in fulfilling their desired potential. The framework is applicable to any organisation of any size that desires a sustainable Six Sigma programme.

2.15.2.12. Implementation of SPC techniques in the automotive Industry: A case study (Prajapati, 2012)

Prajapati (2012) implemented various SPC techniques in an Indian manufacturing entity which manufactures rubber shocker seals. The author implemented the cause and effect diagram and control charts in order to eliminate the causes of variation which lead to the rejection of seals at the final stage. The author concludes that after the implementation of SPC the rejection rate was reduced from 9.1% to 5%.

The target process was identified by evaluating the defect rate of manufactured products. The process was highlighted after establishing a rejection rate of 9.1%. The author identifies the CTQ by selecting the characteristic responsible for the highest rejection rate which is the moulding process of the shocker seals. The Cause and Effect diagram was utilised to identify all the possible sources of variation contributing to the defective mould characteristic. Upon identification of the metrics, preventive actions are set in place to correct the defects. Monitoring of the process using the control chart continues until the next assignable cause variation is detected. The case study thus entails a simplistic model of variation identification using the control charts from where the cause and effect diagram is used to identify the sources of variation. Subsequently the source of variation is removed and the process monitoring continues via the control chart.

2.15.2.13. Quality improvement using statistical process control tools in glass bottling manufacturing company (Awaj et al., 2013)

Awaj, Singh and Amedie (2013) pursued the implementation of SPC in a glass bottle manufacturing company. The focus on waste reduction by minimising the manufacturing of defective products. The study also aimed at raising awareness and coaching employees in problem-solving and SPC tools. The study entailed the observation and evaluation of the production line and its employees.

The product of this study does not have a clearcut implementation framework, however the steps applied in order to reduce process variation and eliminate unnecessary manufacturing waste were clearly explained. The company implemented three SPC tools in order to reduce the manufacturing of defective material.

Pareto charts

The Pareto chart was applied for process prioritisation. Historical data was used and analysed using a Pareto diagram to identify the most common causes of defects (discussed in Section 2.7.2.1). The analysis identified five different major contributors to defects, after which an Ishikawa diagram was used to determine the root cause of these defects.

Ishikawa diagram

A brainstorming session was used to utilise the Isihkhawa diagram and identify possible root causes. The article provides a detailed explanation on how to facilitate and proceed with the brainstorming sessions in order for them to be efficient and effective. Control charts are then utilised to assess the stability of all the processes under investigation.

Control charts

Historical data was used and plotted on a control chart to assess the stability of the process. This was done prior to the establishment of an improvement action plan based on the Ishikhawa diagrams generated during the brainstorming sessions. The control chart was again generated after the implementation of the improvement action plan to evaluate the process for improvements.

Subsequently, the company will continue this sequence of events on a monthly basis in order to continuously identify and nullify defect-generating issues

2.15.2.14. A case of implementing SPC In a pulp mill (Rantamäki et al., 2013)

Rantamaki, Tianinen and Kässie (2013) developed a guideline to operationalise SPC in a pulp mill production unit. The aim of the study was to highlight special SPC requirements in this specific industry. The SPC initiative was implemented as a case study in a pulp manufacturing company. The initiative was pursued as part of the

company's strategic plan to change from focusing on internal efficiency to being customer-driven, therefore the significance of manufacturing consistent compliant products.

The control philosophy of the pulp mill was supported by a fully automated control system. The plant is operational for twenty-four hours a day, seven days a week and only shuts down for maintenance at planned intervals during the year. The automated control system could however not recognise assignable cause variation nor address the variation. Human intervention was required to restore the process back to its natural state.

The SPC programme was implemented in two phases, which consisted of using the existing process control infrastructure and a newly developed system with an IT application source which was specifically designed for the organisation. SPC was initiated by training selected employees and senior management in order to nurture the statistical thinking culture in the organisation. More employees were trained on basic statistics and problem-solving. Control charts and cause and effect diagrams were then deployed to identify special cause variation and subsequently determine the source of the variation in order to eliminate the source and restore the process to its natural state. The logical flow in Figure 22 was utilised to ensure a quick response to the assignable cause variation. In order to speed up the problem-solving process, cause and effect diagrams of all the monitored parameters have been set up prior to the implementation of SPC. The operator uses these diagrams in conjunction with Figure 22. New-found sources of variation would prompt the review and update of documentation. This ensures continuous improvement and effective problem-solving.

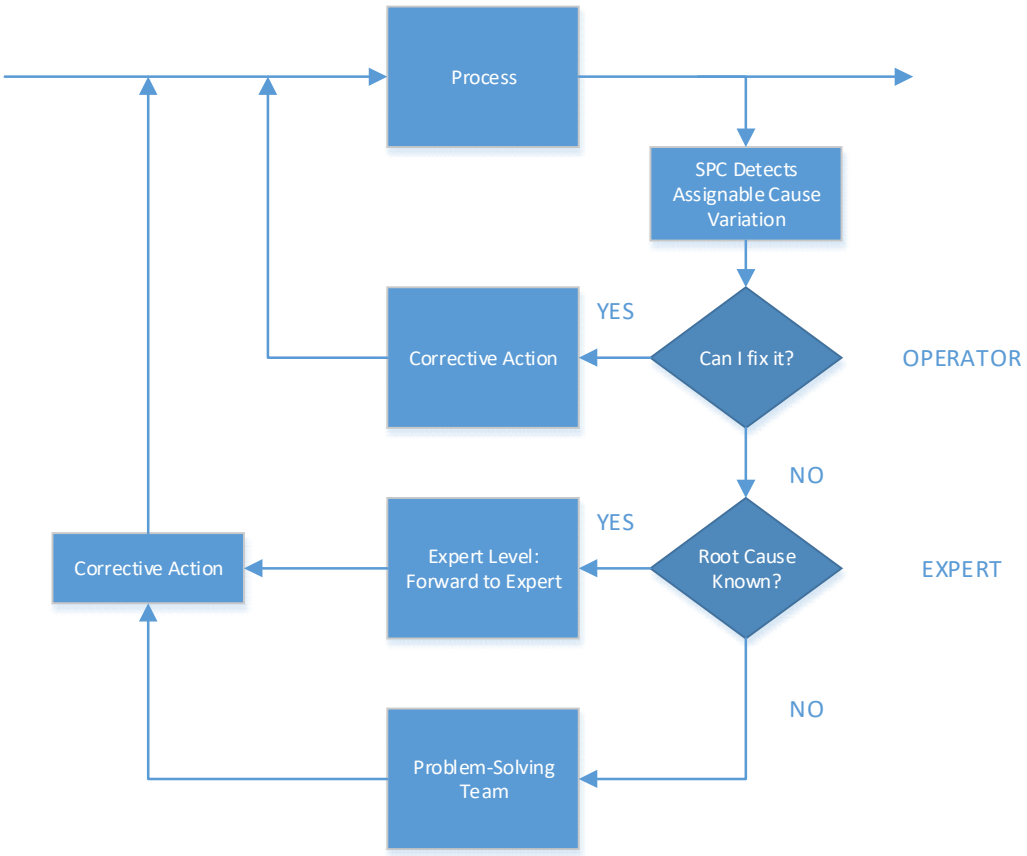


Figure 22: Processing of special cause variation

Source: (Rantamäki *et al.*, 2013)

The authors highlighted the following critical success factors:

- Integration into the business strategy of the organisation.
- Top management commitment.
- Control chart selection and constructions.
- Control chart interpretation.
- Statistical expert in the organisation.
- Statistical thinking.
- Acceptable measurement system.
- Training and education in SPC.
- Metric identification.
- Quality maturity.
- Feedback and learning.

The authors specifically highlight the organisational learning faculty of implementing SPC, as the professional problem-solving and statistical abilities of all the employees improved with the deployment. This statement was specifically supported by tacit problems brought into the open, the improved cooperation between different departments and the general sharing of knowledge. The advantages of SPC were noticeable in the reduction of defects and the positive employee feedback.

2.15.2.15. Attaining competitive positioning through SPC – An experimental investigation from SME (Sharma & Kharub, 2014b)

Sharma and Kharub (2014b) present a conceptual framework with the aim of creating a simple link between theory and application on attaining a competitive business position with the implementation of SPC.

The framework entails an experimental study which tests the formulated theoretical framework as a case study. The study consists of a methodological approach where SPC tools are implemented to evaluate the process performance of a machining SME. The authors conclude that the key factors for the successful implementation of a SPC system are:

- Thorough preparation
- Management commitment
- Human resource management
- Sound measurement and control system

A lack of success with the implementation of the SPC is due to the lack of understanding of the SPC technique and the improper application of SPC within an organisation.

This conceptual framework is based on a four-phase implementation process with the key aspects identified as preparation, definition, measurement and control.

Preparation phase

The preparation phase advises on the prerequisites and the organisational structure required to implement the SPC programme. The preparation phase is divided into the project prerequisites and the organisation structure of the team which will be leading the implementation. The prerequisites focus on the top management aspects, the engineering aspects and the human resource management.

Definition phase

The definition phase consists of the product and process specification and how process control and quality assurance fit in.

Measurement phase

The measurement phase focuses on control chart selection thus highlighting which control chart is the most suitable for a specific process.

Control Phase

The control phase details the process monitoring and the control chart interpretation with an out-of-control procedure.

The authors identified management commitment and involvement, training and education of SPC, the use of pilot projects and an SPC facilitator, teamwork, choice of control charts and the measurement frameworks as aspects which should be focused on to deploy a successful SPC programme.

2.15.2.16. Success factors in the implementation of statistical process control: Action research in a chemical plant (Toledo et al., 2017)

Toledo, Lizarella and Junior (2017) developed a framework for the implementation of SPC, based on 19 critical success factors sourced from literature after performing a systemic literature review. Their focus transcended the conventional sequence of steps to construct and interpret control charts by also focusing on the social, environmental, technical and cultural factors to provide additional assurance of integration into the business processes of the company. The framework was developed, tailored and validated by performing action research. The action research entailed a cyclical process where the authors were part of the team implementing SPC by running the framework through planned phases of intervention, data collection and analyses to better the integration of the SPC programme. The 19 critical success factors are listed in Table 10. The preceding number in the table is the ranking of the CSF based on citing frequency.

Table 10: Critical success factors compiled by Toledo (2017)

Action	Critical Success Factor
Management	1. Commitment and senior management responsibility
	6. Cultural change and communication
	14. SPC use for continuous improvement
	12. Involvement and empowerment of employees
	13. Development of statistical thinking
Organizational	11. Use of pilot study
	9. Use of facilitators or statistical experts
	10. Use of computers and software for SPC
	3. Teamwork
Technique and training	4. Identification and measurement of critical product characteristics
	5. Definition and correct application of control charts
	7. Measurement system analysis in relation to its capability and applicability
	8. Process definition and prioritisation
	2. Education and training in SPC
	15. Documentation and knowledge updating on the process
	16. Interpretation capacity of control charts and the allocation of appropriate actions
	17. Focus on customer satisfaction
	18. Feedback, continuous learning and knowledge sharing
	19. Auditing, analysis and review of control charts for continuous improvement

Table 11 illustrates the developed framework which presents the key critical success factors to be utilised and implemented in a four-stage process. The four phases are planning, definition, implementation and consolidation. The framework systematically progresses through each phase before moving to the next, with three actors responsible for the execution of multiple actions in each phase. According to the authors, the framework is applicable in all industries. The framework is focused on obtaining results and satisfying requirements that are not limited to the chemical industry where the research was conducted.

Table 11: Framework for SPC implementation

<table>
<tr><th>Phase / Responsible</th><th>Planning</th><th>Definition</th><th>Implementation</th><th>Consolidation</th></tr>
<tr><td rowspan="5">Senior Management/ Monitoring Group</td><td colspan="4">Commitment and responsibility of senior management</td></tr>
<tr><td>Pilot project use</td><td colspan="3">Cultural change management</td></tr>
<tr><td>Process definition and prioritization</td><td colspan="3">Education and training in SPC</td></tr>
<tr><td>Project launching meeting</td><td>SPC implementation team definition</td><td>SPC software use</td><td>SPC use for continuous improvement</td></tr>
<tr><td></td><td>Facilitator use</td><td></td><td></td></tr>
<tr><td rowspan="5">SPC Team</td><td rowspan="5"></td><td>Initial education and training in SPC</td><td>Education and training in SPC implementation</td><td>Continuous training and education in SPC</td></tr>
<tr><td>Critical characteristics identification</td><td>SPC software use</td><td>Interpretation capacity and action</td></tr>
<tr><td rowspan="3"></td><td>MSA</td><td>Documentation and process updating</td></tr>
<tr><td>Definition and application of control chart</td><td>Auditing, analysis and review of control chart</td></tr>
<tr><td></td><td>SPC use for continuous improvement</td></tr>
<tr><td rowspan="2">Facilitator</td><td rowspan="2"></td><td rowspan="2"></td><td>MSA</td><td>Auditing, analysis and review of control chart</td></tr>
<tr><td>Definition and application of control chart</td><td></td></tr>
</table>

Source : (Toledo *et al.*, 2017)

2.15.3. Conclusion – Summary of 16 implementation frameworks

Table 12 serves as a synopsis of the 16 reviewed implementation frameworks. While the strengths and weaknesses are deliberated in the table below, the focus of the exercise was to identify the critical success factors as well as to identify functional areas which may require attention in order to deploy a robust SPC programme. Based on the review, the general judgement is that the implementation frameworks reviewed lacked a detailed 'how to', as no article provided a well-articulated process to guide an SME from no SPC system to a fully functional programme. Particular issues were identified as little to no focus on process prioritisation and measurement system analyses. Furthermore, a large amount of attention is dedicated to the formulation of steering committees and teams, and too little on the education of employees on the principles of SPC.

Table 12: Summary of published implementation frameworks for SPC for the 1993 – 2018 timeframe

Title	Reference	Methodology and Strengths	Weaknesses
Statistical process control for total quality	(Ali, 1992)	Four-phase implementation checklist with a detailed analogy on the construction of control plans. Provides a holistic overview of the softer aspects of implementation from planning to consistent process auditing to ensure a sustainable implementation.	The checklist is not commissioned thus it provides no insight as to how it will be implemented. Corrective procedures are mentioned, but lacks problem-solving depth and no mention of measurement system capability.
Effective implementation of SPC in wide area manufacturing systems	(Carter, 1993)	Implementation is based on an organisational model where the focus is education and the key responsibilities of each employee who makes up the model. The author emphasises the use of a detailed software system	Implementation model only focuses on the employees and software. Lacks detail in start to finish implementation plan or roadmap with a major gap in the 'how'. The implementation concept is also stand-alone with no link to problem-solving.
Doing it right the second time	(Kumar & Motwani, 1996)	16-Step Implementation plan which starts with the initiation of a team and top management training. Plan entails a detailed breakdown of steps and logical flow of information.	Lack of detail in product/process prioritisation step, no mention of measurement system capability and also no real detail on effectiveness of implementation. Therefore no real validation.
Implementing SPC in a small organisation: a TQM approach	(Krumwiede & Sheu, 1996)	Two-stage implementation plan. Focus the implementation of SPC by deriving and presenting an organisational model with responsibilities. Secondary focus puts emphasis on the software system used for the implementation.	No mention of measurement system capability. The problem-solving actions and continuous improvement process is ill-defined and cannot be implemented with the amount of information provided
SPC implementation for improving product quality	(Donnell & Singhal, 1996)	Methodology is based on the Lucent Technologies which won the Deming Price. Management-driven framework starting at the COO all the way down to the operators.	Lacks substance on how to prioritise processes. No detail on how to determine critical-to-quality characteristics and also no mention of measurement system capability
A framework for implementation of statistical process control	(Does *et al.*, 1997)	Framework highlights the importance of both organisational and methodological aspects of implementation.	No training of employees is mentioned. The methodological guideline has a very detailed overview, but lacks technical depth which should give the user a simplistic guideline of what to do. Lacks logical flow of implementation steps.

Title	Reference	Methodology and Strengths	Weaknesses
A conceptual framework for TQM implementation for SMEs.	(Yusof & Aspinwall, 2000)	The framework is grounded on the principle of individual progression for each initiative, passing through all six steps of the general methodology before moving on to the next	Framework not validated with no guide on how to operationalise model.
A conceptual framework for the effective implementation of statistical process control	(Antony & Taner, 2003)	Review of four frameworks. Generated framework addresses the shortcomings. Very detailed implementation plan. Advises on how to do the process prioritisation and provides a standard for the MSA.	No validation of implementation framework
The use of SPC Tools for preliminary assessment of an aero engines maintenance process and prioritisation of aero engines faults	(Vassilakis & Besseris, 2010)	Simplistic model developed for a maintenance workshop with a strong focus on problem-solving.	Stand-alone system that does not assist with predictive identification. Nothing mentioned on training and education.
Effective implementation of statistical process control.	(Noskievičová, 2010)	Four-phase implementation plan with a very strong focus on problem-solving. Can be useful for entities with an established SPC monitoring programme which requires direction on problem-solving.	Not suitable for various sizes of entities as the implementation plan lacks detail running up to assignable cause identification. Nothing mentioned on training and lacks detail on process prioritisation.
Six Sigma implementation framework for SMEs – a roadmap to manage and sustain change	(Kumar *et al.*, 2011)	The authors highlight the importance of a step-by-step guideline to assist in the successful implementation of quality initiatives in SMEs and the significance of employee empowerment. The authors proposed the implementation of a five-phase implementation model.	The framework does not explain how to operationalise the model. The authors speak of identifying the best people to train, process and project prioritisation, but no plan is provided on identifying these requirements.
Implementation of SPC techniques in automotive industry: A case study:	(Prajapati, 2012)	Very simplistic model of applying some of the SPC tools. Logical approach by using business metrics such as defect rates to prioritise processes for the application of SPC.	Not very operationally friendly as nothing is mentioned with regards to training and measurement system capability. Explains the detailed technical theory behind the statistical application.

Title	Reference	Methodology and Strengths	Weaknesses
Quality Improvement using statistical process control tools in glass bottling manufacturing company	(Awaj *et al.*, 2013)	The implementation didn't follow the generic SPC implementation route or application, instead three SPC tools were used to identify, evaluate and nullify the common cause of defective products. Straightforward and logical approach to problem identification and solving.	A very basic approach to reducing variability. Although training is mentioned, very little is explained on training and education. Very little is mentioned on measurement system analysis. The application is more reactive than proactive, SPC is not implemented in real time but control charts are compiled for material already manufactured.
A case of implementing SPC in a pulp mill	(Rantamäki *et al.*, 2013)	Programme was based around an IT concept and a significant amount of time was spent on establishing detailed cause and effect diagrams to aid in problem-solving.	Model not feasible for organisations of various sizes as system is based on a highly computerised IT system. Not scalable.
Attaining competitive positioning though SPC – an experimental investigation from SME	(Sharma & Kharub, 2014b)	The authors based their framework on a thorough review of multiple papers. Authors touch on various aspects which are critical from an organisational perspective.	The authors mention the lack of availability of a step-by-step guide for the implementation of SPC. However, they fail to better on this standing by providing a framework with a very high-level approach. SMEs do not have the resources to appoint a steering committee and a process action team as the resources will be utilised in the implementation of quality assurance and quality control and it will be difficult to stretch employees to take charge of a company-wide project of this magnitude.
Success factors in the implementation of statistical process control: Action research in a chemical plant	(Toledo *et al.*, 2017)	Detailed analysis of CSFs. CFS were developed during action research by the authors. This should serve as assurance that all the CSFs are practical.	Developed framework does not seem functional nor is there any structure on how to implement the framework and its actions. Responsibility for certain actions are entrusted to more than one actor in the framework. Framework does not contain problem-solving element or OCAP.

Chapter 3 – Research Methodology

The problem statement in Chapter 1 identifies the need for a framework to support South African SMEs with the implementation of SPC. As mentioned previously, literature lacks a detailed approach on how to implement SPC (Antony & Bhattacharyya, 2010; Madanhire & Mbohwa, 2016; Sharma & Kharub, 2014b). Therefore, this section attempts to address the issue by proposing the process followed to develop a framework for the implementation of SPC. The framework is presented in Chapter 4 based on CSFs and deficiencies identified in the literature review in Chapter 2. The framework is then validated for practicality in Chapter 5.

The research methodology consists of three phases which are the literature review, framework development and the generation of a final framework based on the success of the implementation and the evaluation of the process performance before and after the implementation. The literature survey was performed as a random literature survey coupled with a systematic literature review of SPC implementation frameworks. The research branches into implementation strategies and methodologies used for other continuous improvement initiatives. The objective is to formulate an implementation framework, using the extracted critical success factors and implementation concepts. This research derived a literature-based framework by surveying and critically reviewing peer-reviewed literature to generate an implementation framework for South African SMEs, followed by the validation through a case study.

3.1. Methodology

The proposed methodology is illustrated in Figure 23. The researcher performed action research during the case study validation.

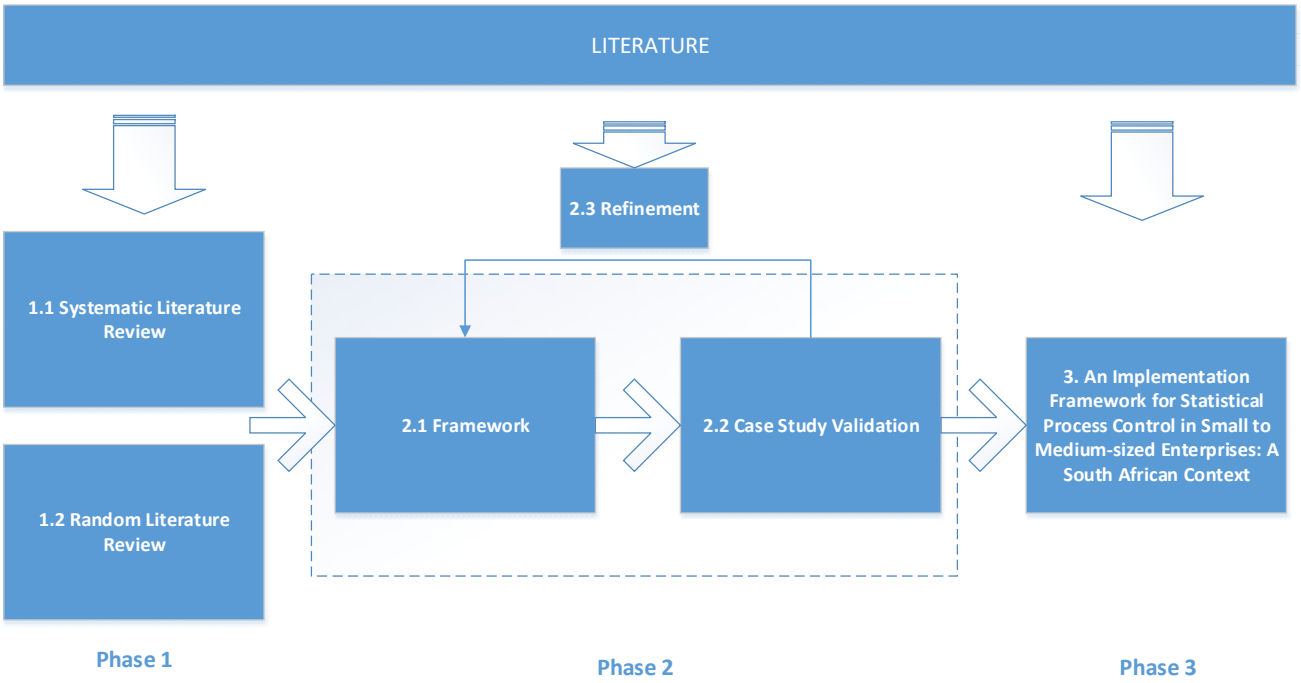


Figure 23: Research process

3.1.1. Action research

Action research involves the creation of theory, while participating in the case study environment (Coughlan & Coghlan, 2002). While traditional research is only aimed at generating theory and the study of a demarcated environment, the application of action research aims to bring about change while generating theory and partaking in the research environment (Bryman *et al.*, 2014). In this specific case study the research aims at exploring the organisational establishment and acceptance of an SPC implementation framework originated from a literature review, while directly dealing with and experiencing the problems at hand. The necessity of a functional framework is highlighted with the failure of the previous attempt. The research aims to develop a framework and to test the framework in the case study environment by partaking in the implementation of SPC. By using action research the researcher aims to contribute to both academic theory and the practical implementation of SPC. Although the core aim of this research project is the implementation of SPC at one facility, using the iterative process of the research method the framework can be refined and improved for implementation at other facilities. Figure 24 is an extension on the proposed Figure 23 and expands on the aspects of action research and how it fitted into the proposed research methodology. The relevance of concepts in the figure below are further explained in Table 13.

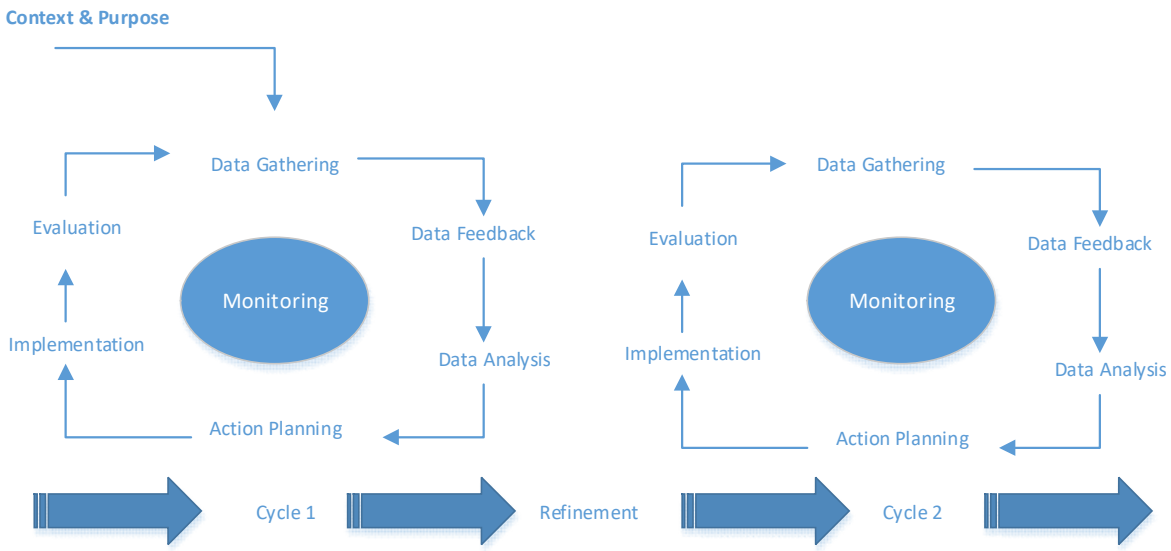


Figure 24: Action research cycle adapted from Coughlan and Coghlan (2002).

Table 13: Explanation of action research concepts as acknowledged in this research study

Concept	Thesis Concept	Location in research study
Context and purpose	Problem statement	1.1
Data gathering	Literature review	2.15
Data feedback	Literature review	2.15
Data analysis	Literature review	2.15
Action planning	Framework development	Chapter 4
Implementation	Framework Implementation	Chapter 5
Evaluation	Process performance evaluation	Chapter 5 and Chapter 6

3.1.2. Research methods

The research approach is mainly qualitative as the research study produced a supporting framework using existing literature. However, quantitative aspects are present in the study as measurement data was collected in order to evaluate the effect of SPC on the overall process performance, using analytics. The quantitative aspect uses a hypothetical approach as process performance is tested, with the result conveying a positive or a negative influence on the process. For the data analytics aspects, Minitab® statistical software was used. The software is widely used in the quality, six sigma and continuous improvement area (Montgomery, 2009).

3.2. Phase 1: Literature review

A random and systematic literature review was utilised to ensure a transparent and reproducible manner of obtaining and reviewing literature without sacrificing articles which the author saw as insightful. A total of

16 articles were selected for review after cross-referencing the data sources obtained using the two review methods.

3.2.1. Systematic literature review

The systematic review was performed using a five-step methodology proposed by Denyer & Tranfield (2009). Table 14 illustrates the sequence of the five steps. This approach ensures that the reviewed information sources are obtained in a systematic, transparent and reproducible manner. The systematic review provides confidence and assurance in the quality of the review as it is replicable, transparent and thorough (Tranfield, Denyer & Smart, 2003).

Table 14: Steps followed for systematic review as proposed by Denyer & Tranfield (2009)

Step	*Aim*	*Output*	*Location in paper (thesis sections)*
(1)Question formulation	*To define the study objective.*	Research question formulated	Chapter 3.2.1.1
(2)Locating studies	*Selection of databases Search terms definition*	Databases and research terms identified and applied. Returned 671 sources	Table 15
(3)Study selection and evaluation	Define criteria on which information sources are included and excluded and sort accordingly	Titles and abstracts scanned and 139 articles selected. A clear SPC implementation framework, guideline or strategy must be present	3.2.1.3
(4)Analysis and synthesis	Analysis of information sources: empirically and relevant to research question	Data extraction and literature review	2.15
(5)Reporting and using the results	Report clear process of review	Detailed review, processes, results, analysis and gaps	Chapter 4

Adapted from (Denyer & Tranfield, 2009)

The first three steps of the review process deal with the definition and demarcation of the review process. This is followed by the selection of resources and the inclusion of the resources as defined by the researcher.

3.2.1.1. Research question formulation

Figure 25 illustrates the CIMO logic used to formulate a research question to define the review protocol for the systematic literature review (Denyer & Tranfield, 2009).

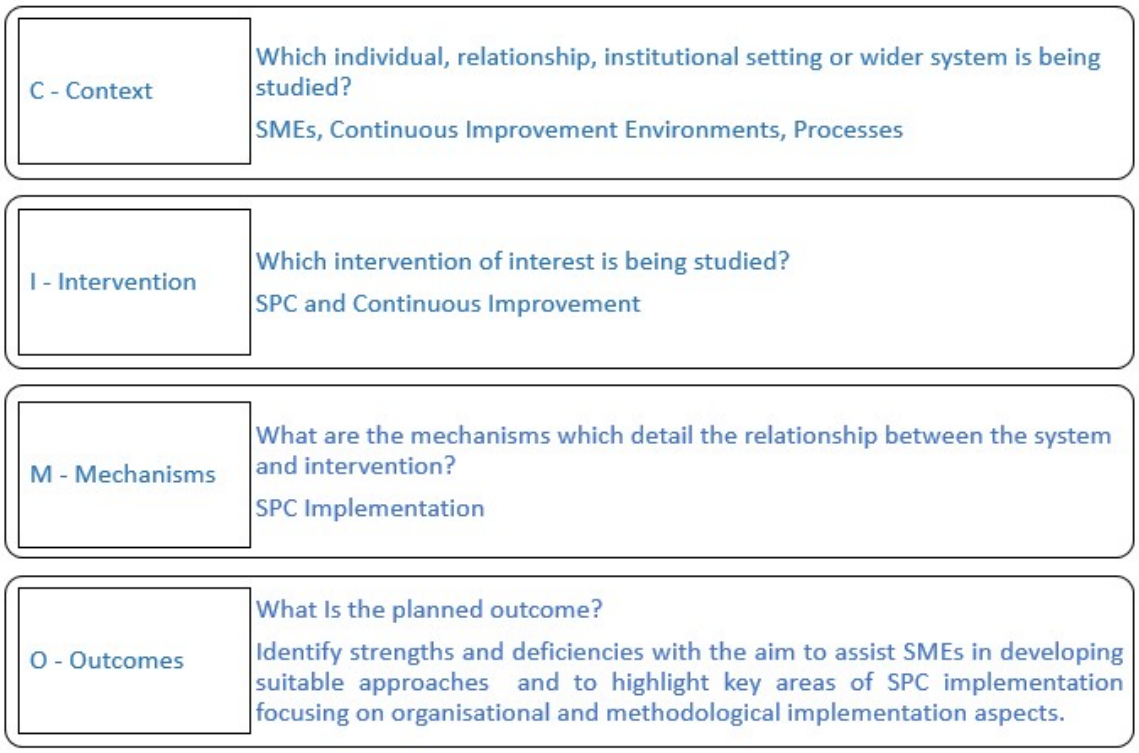


Figure 25: Question formulation for the systematic literature review using the CIMO logic adapted from Denyer & Tranfield (2009)

3.2.1.2. Locating studies

The collection of information sources was performed using online databases. A summary of the databases and search terms can be viewed in Table 15. Due to the difference in functionality of each database, terms and location of terms used differ.

3.2.1.3. Study selection and evaluation

Studies were located as illustrated in Table 3. Given the vast number of documents returned when using the term “SPC”, the search was refined as documented in the table below. The search location (e.g. abstract or title) was used based on the functionality of the database. Documents were scanned and selected based on their titles and abstract. The document search was then reduced to a final 14 articles based on scope relevance, duplication of articles and article accessibility. A clearly defined implementation framework or guideline was set as the inclusion criteria.

Table 15: Summary of locating and selection of studies

Research Process	
Boolean search string (ProQuest)	"SPC" AND "FRAMEWORK" "SPC" AND "IMPLEMENTATION" "STATISTICAL PROCESS CONTROL" AND "FRAMEWORK" "STATISTICAL PROCESS CONTROL" AND "IMPLEMENTATION" "SPC" "STATISTICAL PROPCESS CONTROL"
Boolean search string (Google Scholar)	allintitle: spc"implementation" allintitle: statistical process control "implementation"
Boolean search string (Web of Science)	"SPC" AND "FRAMEWORK" "SPC" AND "IMPLEMENTATION" "STATISTICAL PROCESS CONTROL" AND "FRAMEWORK" "STATISTICAL PROCESS CONTROL" AND "IMPLEMENTATION"
Data base search, location & articles returned and selected	ProQuest (Title and Abstract) – 470 (97 Selected) Web of Science (Title) – 70 (5 Selected) Google Scholar (Title) – 131 (37 Selected)
Period	1989 – 2018
Number of papers returned	671
Number of papers selected based on title and abstract	139
Number of papers reviewed (removed duplicates and papers irrelevant to scope)	14

The frameworks focused on SPC, but are used in various industries and countries. Other continuous improvement initiatives were excluded to focus on the implementation of SPC and due to a restricted timeframe to screen articles. The presence of statistics in both Six Sigma and TQM suggest valid implementation frameworks which can be applied when implementing SPC.

3.2.2. Random literature review

The random literature review was performed as a general search for articles relevant to the implementation of SPC and other continuous improvement initiatives. Initiatives included, but were not limited to SPC, Six Sigma and TQM. The articles were screened and selected as described in Section 3.2.1.3. The articles were cross-referenced with those obtained in the systematic review and a total of 16 articles were identified as suitable for this study. The lack of statistical presence in LEAN manufacturing led to the omission of the continuous improvement initiative.

3.3. Phase 2 Framework development

The core of the framework development section was the review of 16 implementation frameworks. These articles were reviewed and assessed for critical success factors and effective implementation frameworks and strategies. Deficiencies were identified and acknowledged in the review section. The review was performed in Section 2.15 with Table 12 and Table 16 portraying the main results from the literature review.

3.3.1. Framework development

The proposed framework was constructed using the identified CSFs and deficiencies as the baseline aiming at presenting a simplistic, yet effective implementation framework for SPC. The framework development is discussed in Chapter 4. The structure of the framework focuses on the three key areas mentioned below.

1. Preparation
2. Implementation
3. Problem-solving

Each area addresses deficiencies identified in the review section. The three phases are based on extracts from the literature sources.

3.3.2. Validation – Case study

The validation of the developed framework was in the form of a case study. The researcher is an employee in the case study environment and as such evaluated the effectiveness and efficiency of the framework by following the proposed procedure. The framework was evaluated on sustainability; additionally the effect of SPC on process performance was assessed using action research.

3.3.2.1. Sustainability

The sustainability of the deployment was evaluated on the acceptance and integration of the programme into the organisation under evaluation. A sustainable system that is accepted and integrated into the daily operations of the company should have a prolonged effect on the quality of the products of the facilities. Affected employees will take ownership of such an integrated system which will develop longevity and thus ensure a robust and sustainable system.

3.3.2.2. Framework performance

The framework performance is measured on the practicality of the framework and how well it was executed during the validation phase. This section will be supported by Chapter 5 and the complexity of executing the implementation. Therefore, this relies on the author's impartial opinion on the efficiency of the framework and how it can be improved.

3.3.2.3. Process performance - SPC

Process performance of Statistical Process Control implementation will be measured in terms of improvement in quality (Sharma & Kharub, 2014b). This requires proof of a reduction in scrap, rework and rejects (manufacturing of defective material) and should subsequently lead to a reduction in the failure costs. However, these are all long-term effects, therefore the process will be measured by assessing the process capability post and prior to the deployment of statistical process control.

3.4. Phase 3: Implementation framework

The final framework was a reviewed version of the initially developed framework which was implemented. The final framework was refined where feedback and observations collected during the deployment and operational phase of the SPC programme were collected and acknowledged. This information was used to refine and improve the framework before implementation to other areas of the manufacturing facility. Upon completion of the validation and refinement section the final developed framework were constructed and presented as the product of the research study.

3.5. Conclusion

The approach employed in this research study involves the review of current published literature with the aim of extracting an implementation framework, which will be validated using participatory action research. The detailed methodology is explained above with the main steps being:

1. The literature review.
2. The framework development.
3. The implementation of the framework in the case study environment.

The next chapter discusses the development of the framework for the implementation of SPC by building on the literature reviewed in Chapter 2.

Chapter 4 – Framework development

The preceding chapters elaborated on the literature relevant to SPC, the methodology used for this research study and the reviewed published frameworks on which the proposed implementation framework will be based. This section builds on the preceding chapters by attempting to address the identified deficiencies and incorporating the CSFs into an implementation framework for SPC. The framework is presented here as the product of this research study and is derived from the methodology discussed in Chapter 3 and the literature review performed in Chapter 2. The framework aims to address the objectives highlighted in Chapter 1 and is validated by means of a case study in Chapter 5.

Table 16 illustrates the frequency at which each of the critical success factors was cited. Recognising the published frameworks as the platform, this section develops a framework which aims to provide support using detailed guidelines for the implementation of SPC, which could aid SMEs.

4.1. Summary of critical success factors

The CSFs were identified per article. These factors are those which are mentioned as critical to the successful implementation of SPC. A total of 81% of the articles mentioned training and education as a critical success factor where 69% of the same reviewed articles mentioned management commitment as a critical success factor; this was in contrast to the 13% which mentioned statistical thinking.

Table 16: Critical success factor for the implementation of SPC

CSF	(Ali, 1992)	(Carter, 1993)	(Krumwiede & Sheu, 1996)	(Kumar & Motwani, 1996)	(Donnell & Singhal, 1996)	(Does et al., 1997)	(Yusof & Aspinwall, 2000)	(Antony & Taner, 2003)	(Noskievičová, 2010)	(Vassilakis & Besseris, 2010)	(Kumar *et al*., 2011)	(Prajapati, 2012)	(Awaj et al., 2013)	(Rantamäki et al., 2013)	(Sharma & Kharub, 2014a)	(Toledo et al., 2017)	**COUNT**	**% articles**
Awareness					x	x					*x*		x		x	*x*	**6**	**38**
Customer Focus			x	x		x				x	*x*		x	x		x	**8**	**50**
Employee Empowerment			x		x	x			x	x						x	**6**	**38**
Employee Involvement	x		x			x			x	x			x		x	x	**8**	**50**
Integration into the Business Strategy	x	x	x	x						x	*x*						**6**	**38**
Management Commitment		x	x	x	x	x	x	x					x	x	x	x	**11**	**69**
Planning	x	x	x			x				x			x		x		**7**	**44**
Statistical Thinking												x		x			**2**	**13**
Teamwork	*x*	x	x		x	x	*x*				*x*		x		x	x	**10**	**63**
Training & Education	x	x	x	x	x	x		x		x	*x*		x	x	x	x	**13**	**81**

Critical Success Factors ranked as the Top 6, as illustrated in the above table:

1. Training and education
2. Management commitment
3. Teamwork
4. Employee involvement
5. Customer focus

6. Planning

Adding to the CSFs, the articles were reviewed and analysed for deficiencies. These deficiencies are listed in Table 12.

4.2. Summary of deficiencies and proposed solutions identified in review of implementation frameworks (2.15)

According to the reviewed frameworks the most commonly identified gaps are a lack of focus on:

1. Measurement system capability
2. Process prioritisation
3. Identification of critical to quality characteristics, which can be associated with process prioritisation.
4. Training and education
5. Validation of the framework
6. Step-by-step procedure with a logical flow
7. Problem-solving

The following section combines all the identified requirements into a functional implementation framework for the implementation of SPC.

4.3. Framework development

This section formulates a detailed framework by developing a step-by-step implementation plan based on the critical success factors identified in the preceding chapter and the gaps identified in Section 2.15. The framework zooms in on the deficiencies identified in Table 12 coupled with the CSFs in Table 16 to provide a holistic approach to the implementation of SPC.

The proposed framework is illustrated in Figure 32 consisting of three phases divided into twelve steps. The three phases cover planning, implementation and problem-solving. The twelve steps are discussed below to highlight their importance to the SPC framework.

The framework follows a logical flow of steps for implementation and aims to guide the user from start to finish. The ranking of the deficiencies and CSFs does not indicate their position in the framework but highlights the importance of the concept to the implementation of SPC.

4.3.1. Pretraining for management

The problem statement highlights the failure of the maiden SPC programme, which is the primary motive for pursuing a detailed SPC implementation framework. The initial attempt at the implementation of SPC failed due to the lack of understanding of SPC technical principles and benefits. In order for management to

mindfully commit to SPC, prior experience demands the launch of SPC implementation with pretraining of senior management on the principles and benefits of SPC (Kumar *et al.*, 2011). This provides confidence to management which may trickle down and ensure a positive approach when motivating employees and allocating resources to support the SPC programme.

4.3.2. Management commitment

Management commitment was highlighted as key to the implementation of SPC (and other continuous improvement initiatives) as management support is required to ensure that adequate resources are available to pursue the SPC initiative (Ali, 1992; Carter, 1993; Sharma & Kharub, 2014b). The first step for the majority of reviewed implementation frameworks involved obtaining complete commitment and support from management to the SPC initiative. The implementation of SPC should thus occur with a top-down organisational structure and management should allow the commitment and allocation of adequate resources (Donnell & Singhal, 1996). CI initiatives should be initiated by top management, implying management commitment is guaranteed once a programme like SPC is launched as they serve as sponsors for the project (Lim & Antony, 2016). A cultural shift is required to adopt statistical thinking which highlights the value of SPC, this puts the focus on management to drive the change in culture (Carter, 1993). Management needs to own, support and drive the implementation of SPC (Kumar *et al.*, 2011). This is driven by understanding, which is obtained with the pretraining of management on SPC.

4.3.3. Awareness

The acknowledgement of variation in processes, in addition to the awareness that there are philosophies such as SPC available is essential (Awaj *et al.*, 2013; Grigg & Walls, 2007; Kumar & Motwani, 1996; Toledo *et al.*, 2017). Awareness should be raised to emphasise the importance of adopting a philosophy such as SPC, highlighting the value SPC would add to a business, coupled with the challenges when embarking on the initiative (Abdul Halim Lim *et al.*, 2015). Awareness is raised by informing, educating and earning the acknowledgement of employees regarding process variation. Given that management acknowledges the presence of variation, process controllers, managers and engineers are permitted to interpret variation and act accordingly. The acknowledgement of variation may also warrant an additional awareness where problems are openly discussed creating a platform for open communication, streamlining attention towards common goals and targets (Rantamäki *et al.*, 2013).

4.3.4. SPC team

Practically, it is impossible for a single employee to bring about change in a manufacturing environment, especially with regards to improved quality and when attempting to implement a fully operational continuous improvement initiative (Hubbard, 2003). The successful practice of SPC demands commitment

and involvement from a dedicated team (Ali, 1992; Does *et al.*, 1997; Hubbard, 2003; Kumar & Motwani, 1996). Therefore, the assignment of responsibilities and the active involvement of team members is critical.

4.3.4.1. Formation of SPC team and assignment of responsibilities

Employees will contribute more willingly and actively to continuous improvement initiatives if they are aware that the problem affects their departments (Hubbard, 2003). Juran & Godfrey (1998) state that the involvement of a cross-functional team promotes the sharing of ideas and experiences and the shared objective to help 'their' organisation achieve the targets will serve as motivation for all. The involvement of various team members from different departments creates the perception of a more superior plan, thus increasing the likelihood of acceptance by employees executing the implementation (Hubbard, 2003; Juran & Godfrey, 1998). Therefore, literature supports the creation of a cross-functional team when implementing continuous improvement initiatives.

The proposed team structure is presented by Carter (1993) but the size and roles of the team are supported by Hubbard (2003) and Abdul Halim Lim *et al.*(2015), who motivate that the team size should be relevant to the company size and should support the current company culture. The SPC team will be composed in the form of a matrix structure to ensure a cross-functional team. Figure 15 illustrates the organisational requirement for an SPC team. These roles are highlighted in various publications and are the minimal requirements to launch, operate and maintain a SPC system. The matrix structure ensures a diverse team with defined deliverables aimed at reducing variation. The roles will be fulfilled by existing employees for whom different levels of training will be required. The extremes are identified as employees who are completely new to the concept of variation and SPC, where the requirement exists for training to raise awareness and to equip the employee with the tools to fulfil their duty in the matrix structure. The team organisational structure is illustrated in Figure 26 and listed below:

1. Management Team Commitment – Enforce management commitment and fully support the program, act as project sponsor.
2. SPC Coordinator and Statistical Expert – Overall responsibility for SPC implementation and coordination.
3. First Line Managers – Coordinate implementation in their area and take part in team meetings.
4. Engineers and Maintenance – Technical support and documentation.
5. SPC Experts – Trained operators facilitate and lead implementation, construct control charts and are responsible for the out-of-control action plan.
6. SPC Drivers and Operators – Responsible for daily monitoring, handover and dealing with out-of-control points.

(Carter, 1993).

The structure is divided into strategic, tactical and operational (see Figure 26 below).

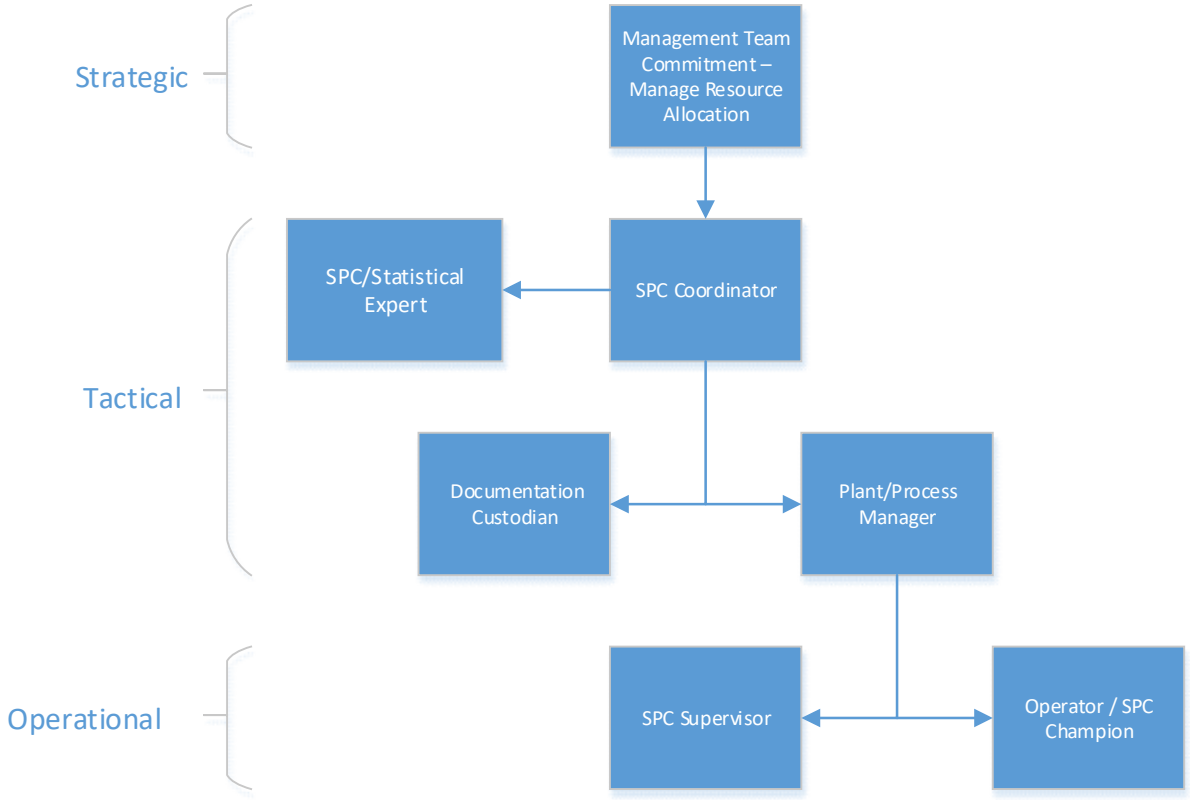


Figure 26: SPC Team organisational structure

Source: Adapted from (Carter, 1993)

4.3.4.2. Teamwork

To implement a continuous improvement initiative, the success of the project will greatly depend on the interaction of the various parties to ensure each requirement is executed promptly and effectively (Carter, 1993). The success of SPC is dependent on the commitment and dedication of each employee, whether a senior manager or an operator (Carter, 1993; Donnell & Singhal, 1996; Krumwiede & Sheu, 1996).

4.3.5. Training and education

Employees using or interacting with the SPC system will require training on the concepts, tools and benefits of SPC (Cheng & Dawson, 1998; Lim & Antony, 2014; Toledo *et al.*, 2017). Training and education also raises awareness on the importance of having access to a tool such as SPC and the potential benefits for the employees and the company (Sharma & Kharub, 2014a). Therefore, formal and informal training should be provided for all employees. Training can be specialised to the role of the employee in the SPC system (Lim & Antony, 2016). Table 17 illustrates a training programme with set requirements for different levels proposed by Abdul Halim Lim *et al.*(2015).

Table 17: An SPC training programme as proposed by Abdul Halim Lim *et al.* (2015)

Characteristic	Level 1	Level 2	Level 3
Objective	Training on general concepts of SPC	Training on problem-solving skills, basic statistics and control chart interpretation.	Guide the application of control charts and problem-solving
Participant	Company-wide (Strategic, Tactical and Operational)	SPC Team (Tactical)	SPC Operators (Tactical & Operational)
Contents	• Concept of variation • Process stability and capability • Current process control practices and data quality	• Control chart interpretation • Problem-solving • Measurement systems analysis • Descriptive statistics	• Theoretical control chart • Sampling and data collection • Capability analysis and OCAP

4.3.5.1. Documentation

Specific to small organisations, but relevant to any organisation is the generation of manufacturing documentation which will support the implementation of SPC (Krumwiede & Sheu, 1996). The responsibility of providing technical support and the generation of documentation falls on the engineers highlighted by Carter (1993) in Figure 26.

4.3.6. Process prioritisation and SPC studies

The probability of process improvement is significantly higher if SPC is introduced to a process with considerable room for improvement (Abdul Halim Lim *et al.*, 2015). The presence of multiple input and output variables which could directly or indirectly affect critical to quality characteristics creates confusion for those attempting to implement SPC (Efthimiadu & Tham, 1990). The identification of underperforming processes, suitable for SPC implementation is not well documented in the reviewed articles. Therefore, an opportunity for improvement exists to establish a step-by-step guideline which could potentially assist South African SMEs with process prioritisation for the implementation of SPC.

As mentioned in Section 1.2.1 and illustrated in Figure 1, SPC is based on the formulation $Y = F(X)$, where X is the input which requires monitoring to achieve a desirable Y (output) metric (Montgomery & Runger, 2007). A process will only be enhanced if there is genuine room for improvement. The method used to prioritise the process for this case study thus focuses solely on process performance. The determination of the process and metrics will follow the flow as illustrated in Figure 27.

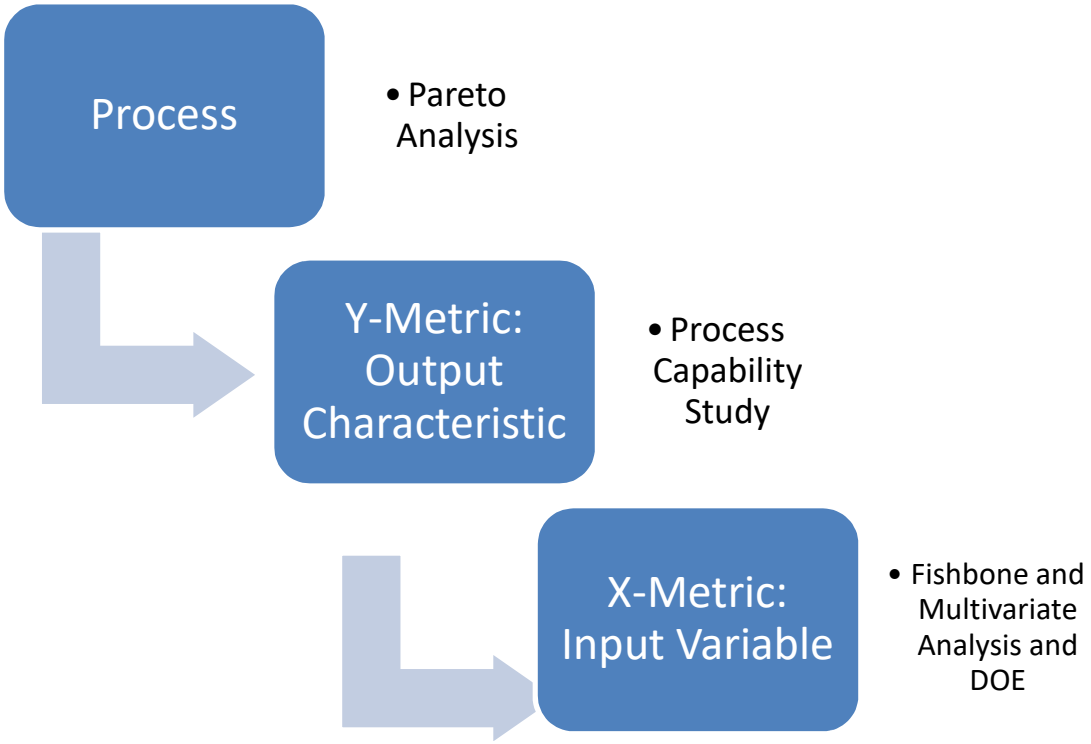


Figure 27: Process prioritisation hierarchy

Process prioritisation will be achieved using three steps as illustrated in Figure 28. This method is aimed at identifying the process, outputs and most critical inputs, in order to improve performance.

4.3.6.1. Step 1

In companies with more than one process, the processes can be ranked by performing a Pareto analysis on all the non-conformances recorded on site (Abdul Halim Lim *et al.*, 2015; Awaj *et al.*, 2013; Oakland, 2003; Vassilakis & Besseris, 2010). The processes can be ranked as projected by the Pareto output, with the most inadequate process highlighted for the pilot study.

4.3.6.2. Step 2

This step elaborates on which output characteristic should be focused on. A capability study can be used to evaluate all the output characteristics and establish, by means of capability indices, the most critical-to-quality characteristics which require monitoring and improvement (Does *et al.*, 1997; Montgomery, 2009). The percentage defects identified in Step 1 will also be specified, meaning the defect with the highest frequency will be focused on coupled with the characteristics identified in the capability study.

4.3.6.3. Step 3

Step 3 entails the identification of the input parameter with the most significant effect on the poor performing output characteristic. This step involves the identification of causal relationships between the input and output variables. For this study fishbone diagrams and a multivariate analysis (regression) can be used to evaluate the effect of the input parameters on the output parameters (Hung & Sung, 2011b). The multivariate chart is the most suitable analytical technique to identify causal relationships between

parameters (Abdul Halim Lim *et al.*, 2015; MacGregor & Kourti, 1995). Regression is a statistical method used to evaluate the statistical significance of the relationship between an input and an output parameter (Montgomery & Runger, 2007). This method quantifies the existence of a causal relationship between characteristics. DOEs are more time and cost-intensive as trial periods are required to identify causal relationships, whereas multivariate analysis is based on historical data.

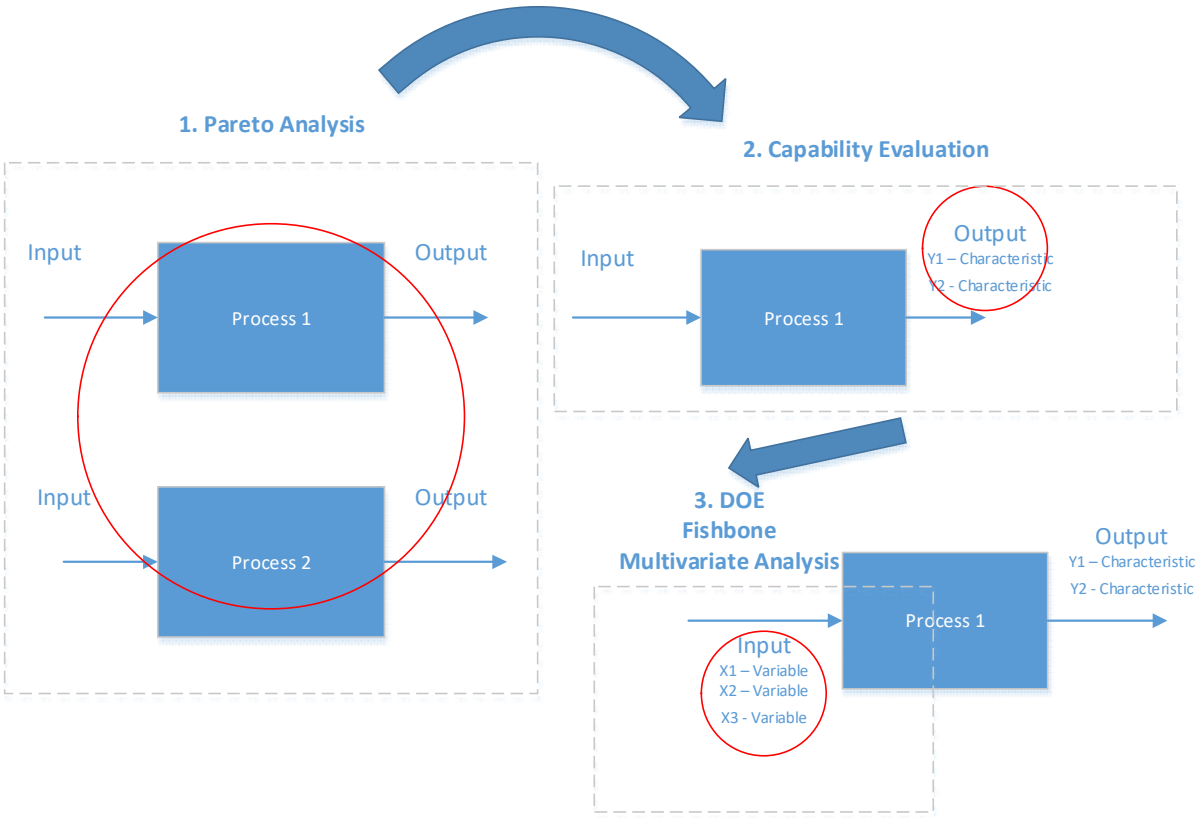


Figure 28: Diagram illustrating flow of process prioritisation steps

Measuring and monitoring requires the use of a measuring system. It is essential to evaluate the accuracy and precision of the measuring system to ensure that the returned values which are plotted on the control charts are the true values of the characteristics being recorded.

4.3.7. Measurement system analysis

As previously mentioned in Section 2.2, data-driven decision-making offers confidence in the approach to decision-making, which affects processes and products as it is based on statistics and measured performance. Measurements are used to validate the consistency of a manufacturing process by evaluating the measurement of a characteristic to a predetermined requirement (Yeh & Sun, 2013). Data is obtained via a measuring process where a value is assigned to a characteristic using a measuring method (AIAG, 2010). MSA entails the validation of the measuring system (all aspects used to quantify a unit of measure e.g. Instrument or system) ensuring the returned values contain only process variation and not measuring system variation

(Abdul Halim Lim *et al.*, 2015; Toledo *et al.*, 2017). A MSA is performed as mentioned in Section 2.2, where the measurement systems of the processes are evaluated for accuracy and precision and the analytical laboratory method evaluated for measurement system capability.

4.3.8. Control chart selection

Control charts are fundamental to the success of SPC as the control chart forms the core of the monitoring and measuring system, by allowing an appropriate form of data analysis to identify the common and assignable cause variation (Toledo *et al.*, 2017). Control charts identify problematic areas by detecting a shift in the process mean or an increase in the data spread (Mahanti & Evans, 2012).

Recapping on the benefits of using control charts as a performance measurement for processes as highlighted by Montgomery & Runger (2007), these are:

1. Proven technique of improving productivity
2. Effective in defect prevention
3. Prevents unnecessary process adjustment
4. Provide diagnostic information
5. Provide process capability information

Control chart selection will be performed as illustrated in Figure 7. Specific datasets require a specific type of control chart (Mahanti & Evans, 2012). The selection of the incorrect control chart could give a skewed indication on the reality of the situation, by highlighting or hiding bad trends and results (Latzko, 2003). Given this, the significance of control chart selection is important and as such the selection process should be aligned with the type of data to be recorded. Variable control charts are appropriate for variable data and attribute charts are appropriate for attribute data (Mahanti & Evans, 2012).

Pending the control chart selection, the implementation platform is established focusing on data recording and the construction of the control charts.

4.3.9. Implementation platform

The implementation platform forms the core operational and functional baseline of the SPC programme as the efficiency of the programme will depend on the platform. Carter (1993) and Rantamäki (2013) both opted for computerised systems in order to automate the capturing of data and the generation of control charts. However, the drawback of a computerised system is the possibility of being unable to share the data and process performance information, limiting the company-wide distribution of performance data (Grigg & Walls, 2007). Smaller and older facilities manage to operate an effective SPC system using paper-based

control charts (Grigg, 1998). The onus is on management and the SPC coordinators to determine the best and most effective platform for the implementation of SPC.

4.3.10. Establish SPC baseline

The step entails the collection and processing of existing data prior to the launch of the SPC programme, in order to establish a performance baseline or a current state. The baseline is significant as it allows for the comparison of the identified metrics performance at the start and end of the programme (Gejdoš, 2015). This provides a clear indication on any significant process improvement.

4.3.11. SPC cycle

Following the completion of the preparation phase, the proposed next step is the SPC cycle. The cycle consists of the tools and steps required to distinguish between assignable cause and common cause variation.

1. Data finding

Data finding is the sampling and recording of data of the metrics to be monitored. Important to the control charts is the sampling. For effective sampling the method, frequency and control points need to be identified (Abdul Halim Lim *et al.*, 2015; Montgomery, 2009).

2. Construct control charts

The principles of control chart construction can be found in Chapter 6.2 of Montgomery's *Introduction to Statistical Quality Control* (Montgomery, 2009). The data recorded in the preceding section is used to generate the control chart. The validation section provides more detail on control chart construction as it is dependent on the implementation platform.

3. Interpretation of control charts

The zone identification criteria are illustrated in Figure 29. The operator will be triggered to action when the process resides in the action zone section A (Romdhane *et al.*, 2017).

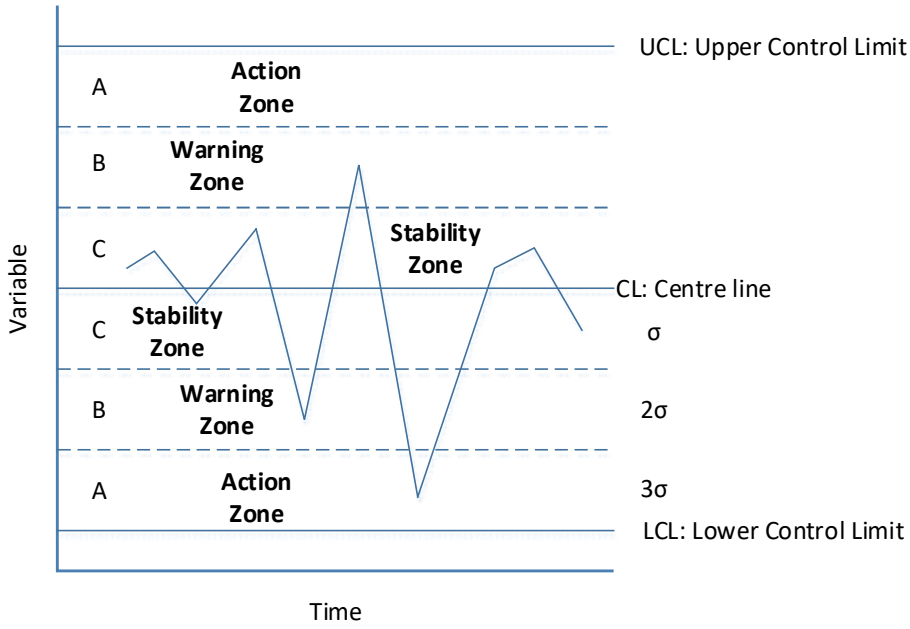


Figure 29: Zone identification for the implementation of SPC

Adapted from: (Romdhane *et al.*, 2017)

4. Assignable cause identification

The points below should raise concern and should be investigated:

1. One or more points outside of the control limits.
2. Two or three consecutive points outside the two-sigma warning limits but still inside the control limits.
3. Four or five consecutive points beyond the one-sigma limits.
4. A run of eight consecutive points on one side of the centre line.
5. Six points in a row steadily increasing or decreasing.
6. Fifteen points in a row in zone C (both above and below the centre line).
7. Fourteen points in a row alternating up and down.
8. Eight points in a row on both sides of the centre line with none in zone C.
9. An unusual or non-random pattern in the data.
10. One or more points near a warning or control limit.

(Antony & Taner, 2003; Romdhane *et al.*, 2017; Sharma & Kharub, 2014b)

5. Evaluate capability & 8. Reassess capability

The capability evaluates the uniform distribution of a characteristic at a specific time coupled with the prediction of the possible defects per million opportunities (Montgomery, 2009; Montgomery & Runger, 2007). The capability study statistically evaluates the performance of the process relevant to the specification tolerance required by the customer (Abdul Halim Lim *et al.*, 2015). This evaluation will be performed using

Minitab® Statistical Software. The capability study, its requirements and performance measurement technique are discussed in Section 2.3.

6. Sanction capability

A process will be deemed capable once it complies with the requirements as stated in Table 2.

7. Minimise common cause variation

The OCAP is the out-of-control action plan and is the tool set in place to assist with the root cause analysis and problem-solving (Abdul Halim Lim *et al.*, 2015). The following steps are all covered in the OCAP which is discussed in Section 4.3.12.

9. Assignable cause identification

Refer to the OCAP 4.3.12.

10. Improvement action selection plan

Refer to the OCAP 4.3.12.

11. Realisation and verification of action for improvement

The corrective action is then installed and monitored for effectiveness. The process can be re-evaluated for capability upon successful introduction of the corrective action.

12. Process maintenance and documentation update

Once the implemented action has been evaluated as effective, efficient and permanent, the manufacturing documentation of the facility can be updated to ensure that it becomes part of the standard operating procedures (Carter, 1993; Hubbard, 2003; Montgomery, 2009). This ensures continuous improvement as a new baseline is established.

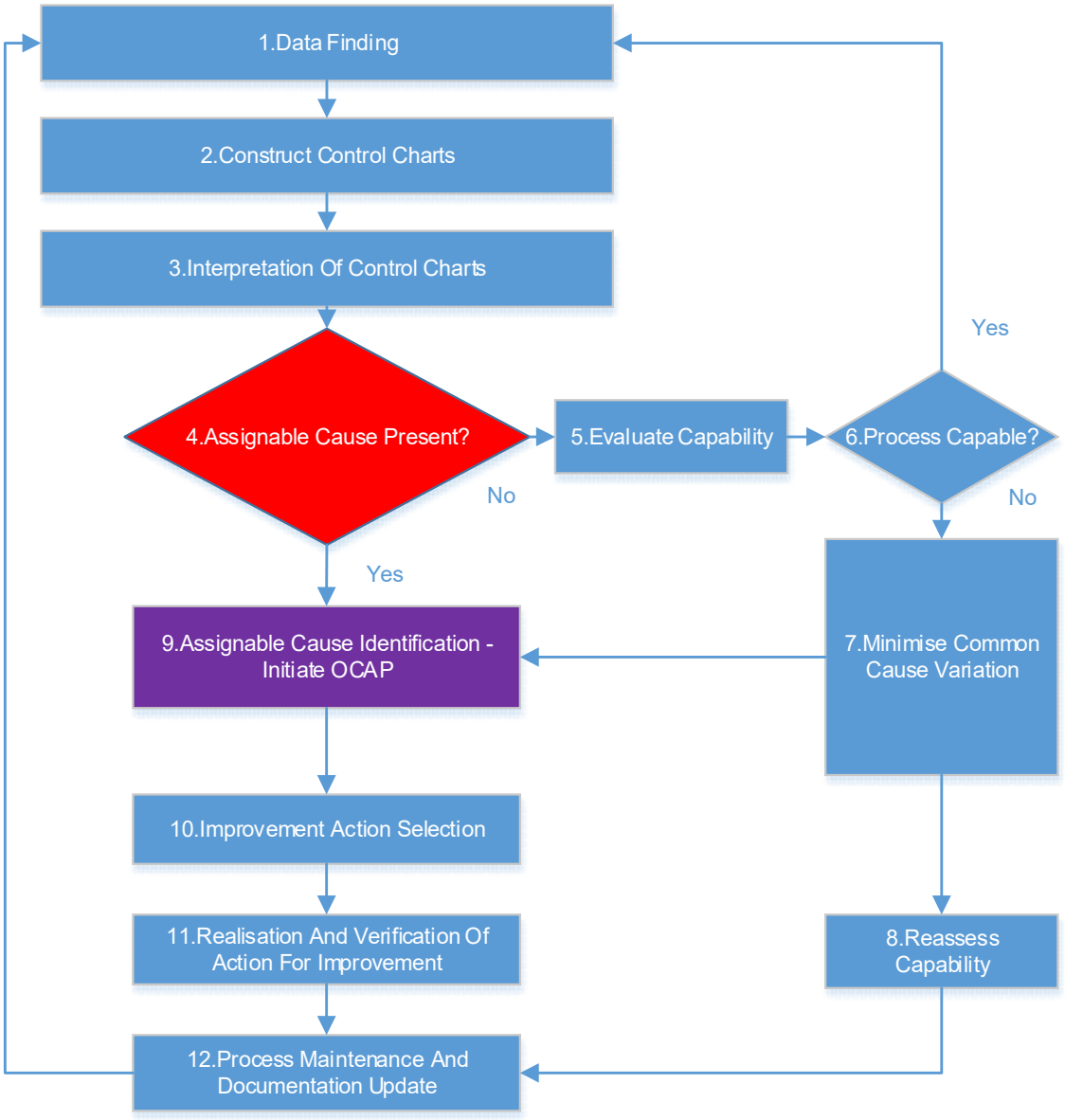


Figure 30: Graphical illustration of the SPC cycle – Phase 2

Source: Adapted from (Antony & Taner, 2003; Noskievičová, 2010; Sharma & Kharub, 2014a)

4.3.12. Problem-solving – Out-of-control action plan

The main objective of an SPC programme is the reduction of variation of an output characteristic by identifying, changing and controlling an input variable (Noskievičová, 2010). The identification of assignable cause in an output characteristic is triggered by a control chart, however the identifying and removal of the source of the assignable cause variation is achieved by supporting your SPC programme with a well-integrated and functional problem-solving methodology (Halim Lim *et al.*, 2015). This provides the diagnostic capability which increases the likelihood of variation reduction in processes (Noskievičová, 2010). Therefore, the problem-solving aspect of an SPC programme is vital as this maximises the potential value to be gained from SPC.

The action plan below was adapted from (Rantamäki *et al.*, 2013). The cycle loops through the detection of assignable cause variation and the sequence of how the operator should react to the identification of an assignable cause variability. This is Step 9 of the SPC cycle illustrated in Figure 30.

The diagram in Figure 31 illustrates the cycle for when assignable cause has been detected; it is called the out–of-control action plan. The OCAP will be implemented with a pre-completed and configured FMEA as the basis of the problem-solving as this will ensure significant timesaving on improvement actions and problem-solving (Romdhane *et al.*, 2017). The 8D problem-solving methodology will be used in situations where the anticipation of using the FMEA is ineffective.

The cycle is divided into two critical sections of involvement. The first is the operator level of control. This is done to ensure that employee empowerment is integrated into the programme as well as organisational learning, as with this step the operator will not only be responsible for solving the problem, but it will also be expected of the operator to acknowledge all shortcomings of the FMEA and prompt the SPC facilitator to update the documentation to ensure that the operator will be able to fulfil their duty when a similar problem occurs. The FMEA is a tool used to identify and prioritise sources of variation, failures and areas and present possible corrective actions (Montgomery, 2009).

The operator will be expected to:

1. Identify that assignable cause variation is present in the process.
2. Use the failure modes and effect analyses report to address the problem.

If the operator is unable to address the problem using the FMEA, facility management may assist with the problem-solving. Facility management then has the option to pursue the problem themselves or assign it to the cross-functional team to assist. This will take longer to restore the process to its normal state. The main aim should always be to ensure the safest and most effective method of addressing the issue. A key outcome is the review and update of the manufacturing instructions and standard operating procedures (Carter, 1993).

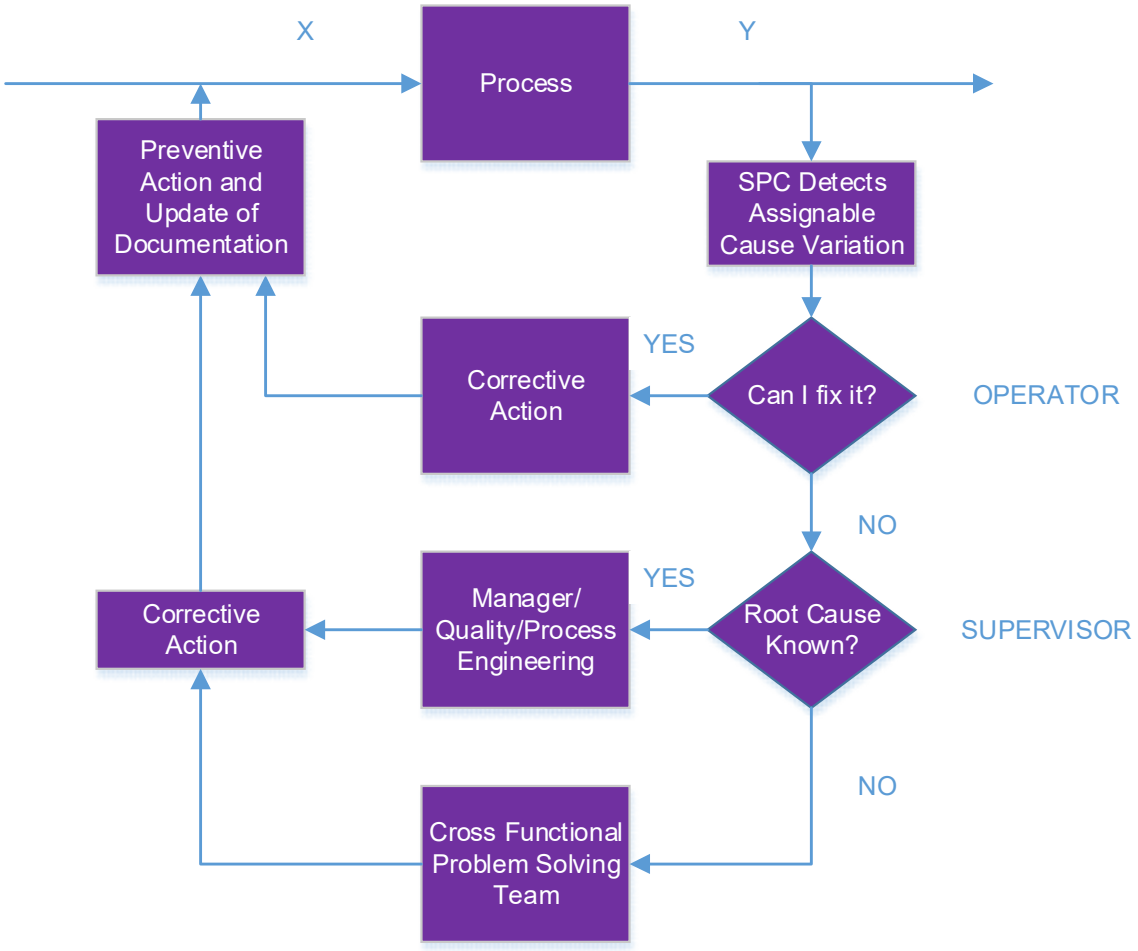


Figure 31: Graphical illustration of the out-of-control action plan – Phase 3

Source: Adapted from (Rantamäki *et al.*, 2013)

4.4. An implementation framework for the implementation of statistical process control

Figure 32 illustrates the proposed framework for the implementation of SPC for SMEs. The framework was constructed based on a thorough literature review performed in Chapter 2 and consists of concepts and principles derived from various literature-based papers discussed in the preceding subsections. The proposed framework serves as the core functional roadmap to follow when implementing SPC with Figure 30 and Figure 31 as supplementary frameworks, guiding the practical implementation aspects and phase one of the main framework guiding the organisational aspects.

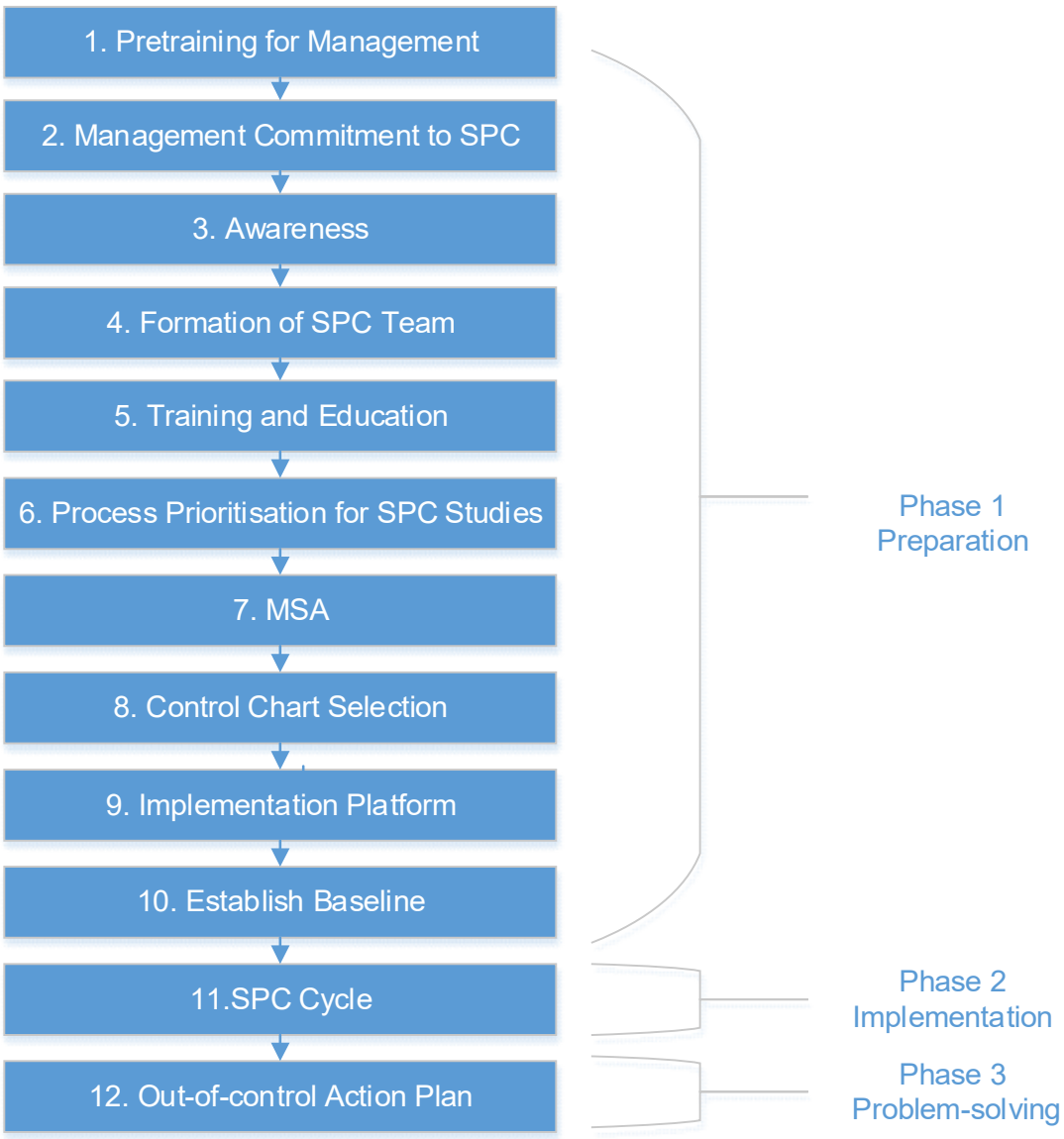


Figure 32: A framework for the implementation of statistical process control

4.5. Conclusion

A framework has been generated using a systematic literature review, coupled with a random literature review. Critical success factors and deficiencies sourced from existing published literature and highlighted in Chapter 2.15 and in Chapter 4.1, formed the building blocks of the framework presented in Chapter 4.4. The following section will employ the developed framework and discuss the implementation of the framework, as a case study in a South African SME, using participatory action research. This step serves as validation of the proposed framework.

Chapter 5 – Framework Validation – A case study

The preceding chapter proposed an implementation framework for statistical process control. This chapter documents the validation of the framework by means of a case study implementation at a manufacturing facility. The framework will be measured against the objectives set out in Chapter 1. The key objective is to provide practical assistance to the organisation while attempting to implement SPC, with the secondary objective being the improvement of process performance by reducing variation. This is done by establishing a predictable process.

The case study environment is a chemical manufacturing entity with approximately 110 employees. This verifies compliance with the requirements as set out in Table 7 for SMEs. The site manufactures chemical raw materials for further downstream processing, highlighting the importance of the site to the total supply chain. The need for continuous improvement exists as manufacturing waste is generated when material has to be reworked and scrapped, generating failure costs. The company has set a benchmark of 3% failure cost as a percentage of production costs, however the value increased to 7% in 2018 suggesting a problem in manufacturing efficiency, as well as a major deviation from the target of zero defects.

Literature supports the notion of management commitment as the base requirement for company-wide projects, which involves employees and their daily duties. The same precedent is set for SPC, where the first step of the framework highlights the informing and 'convincing' of senior management as to why SPC is required in their organisation. Support can only be granted when the requirement and approach is understood.

5.1. Pretraining and management commitment

The value of management commitment to the success of SPC is highlighted at various stages during this research study. The importance of management support throughout the whole implementation process is crucial, hence steps involving management are the first to be addressed to ensure sufficient support and resources for smooth integration of all the succeeding steps.

Management commitment was obtained prior to start of the SPC implementation. However, the lack of technical and general knowledge on SPC had to be addressed by providing a general workshop session on the core concepts and tools utilised when implementing SPC. The workshop was attended by the general manager, the laboratory manager, operations manager and the executive quality manager. Topics covered included:

- Background information on SPC
- An overview of the proposed project

- Problem statement
- Significance of SPC
- Proposed methodology and
- Proposed timeline

The presentation served as an information session on the significance and the critical technical concepts of SPC. However, the main reason for the presentation was to convince general management of the benefits which SPC might bring to the organisation when implemented and operated appropriately, thereby lessening the effect of the previous failure by substantiating the reason for failure and encouraging the possible effect of a different approach, which guarantees an increased probability for success. The presentation can be viewed in Appendix B.

The general outcome was achieved as the management team was eager to implement SPC by integrating the task of implementing SPC into the contract management of the employees involved. This ensured that resources, however limited, were made available for the implementation of SPC.

5.2. Awareness

Awareness of SPC and its benefits is essential to facilitate the acceptance of SPC by employees. Awareness was raised by presenting the proposed project of implementing SPC at site mass meetings. The benefits and basic functionality of SPC were discussed. The coordinator attended facility 'green floor' meetings in order to directly engage with all employees and to answer and address any concerns and queries regarding the programme. Prior to the training sessions for those involved, all employees received information on the concept of SPC and the benefits it may afford. The focus was on increased probability of manufacturing a more consistent product. The presentation can be viewed in Appendix B. Raising awareness was not a once-off event as afterwards facility managers and the coordinator continuously discussed the potential benefits and impacts leading up to the implementation of SPC. Following the attempt to raise awareness, the team tasked with duties regarding SPC was formed. The coordinator attended weekly green floor meetings at the testing facility and facility α (see Section 5.5). These meetings served as the general platform for continuous improvement allowing for free discussions on value-adding concepts such as SPC.

Highlighting the benefits SPC may afford, specifically to the day-to-day operations, is essential when dealing with a diverse employee group. Experience in the case study environment suggests that programmes such as SPC are difficult to integrate with more experienced employees as they prefer to work according to methods which they are accustomed to. It is easier to convince 'younger' employees of the benefits of SPC, therefore guaranteeing easier acceptance.

5.3. Formation of SPC team

The SPC team was composed of current employees where the SPC duties were tied into their day-to-day responsibilities. The team organisational structure is illustrated in Figure 33 and listed below:

1. Management Team Commitment – General Manager, Executive Quality Manager and Operations Manager.
2. Programme Manager – Engineer: Quality with assistance from Process Engineer.
3. First Line Managers – Facility Managers.
4. Engineers and Maintenance – Technical support and documentation – Process Engineer.
5. SPC Experts – Trained operators facilitate and lead implementation, construct control charts and are responsible for the out-of-control action plan – Facility Supervisor.
6. SPC Drivers and Operators – Responsible for daily monitoring, handover and dealing with out-of-control points – Process Operator.

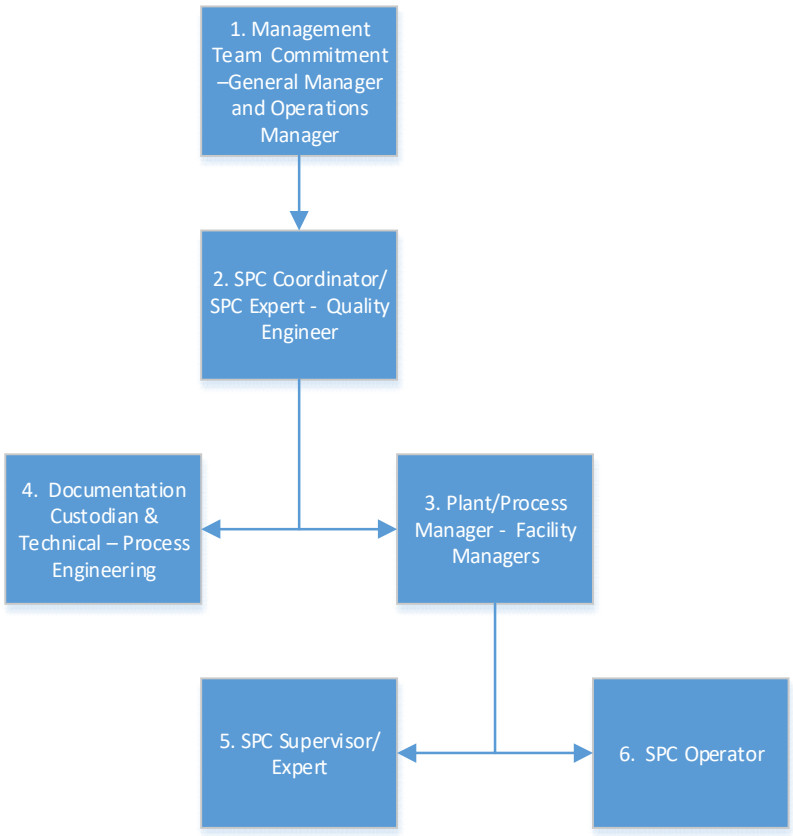


Figure 33: Graphical illustration of SPC team organogram

The team responsibilities are highlighted in Section 4.3.4.1. Given the delegation of roles, each role requires a set of skills and abilities to ensure the project is executed successfully. The following section details the structure and execution of training and education for the implementation of SPC. While the quality engineer completed Steps 1 – 7, inputs were acquired from the entire team and the review of manufacturing documentation compiled for the implementation of SPC was performed by the process engineering manager,

the facility manager and final approval was sanctioned by the site's quality manager. Table 35 (see Appendix C) illustrates the document validation, prior to official configuration of all manufacturing documentation.

5.4. Training and education

The training was structured over a period of three days for four hours each day. During these sessions the basics of SPC were covered using content derived from the lecture notes of the courses the author attended, mainly sourced from AIAG (2005).

5.4.1. Aim of training

The aim is to equip the operators and employees with the necessary tools and skills to contribute to the successful implementation of SPC. Therefore, the outcomes of the training are to:

1. Expose all employees to SPC.
2. Provide a fundamental understanding of the role of SPC within continuous improvement.
3. Establish understanding of how SPC can be used to establish statistical control of critical to quality characteristics.
4. Problem-solving.

5.4.2. Course content

Topics covered while attempting to fulfil the aims and needs of SPC implementation were:

1. Concept of variability
    a. Variability
    b. Standard deviation
2. Introduction to SPC
3. Continuous improvement and SPC
4. Shewart control charts
5. Other types of control charts
6. Control chart interpretation
7. Capability analysis and OCAP

5.4.3. Schedule

A detailed training schedule is illustrated in Table 18. The table highlights three different levels of training which certain employees received, based on their functional role in the programme.

Table 18: Training schedule for all employees

Characteristic	Level 1	Level 2	Level 3
Participant	Company-wide (Strategic, Tactical and Operational)	SPC Team	SPC Team
Contents	• Concept of Variability • Introduction to SPC • Continuous Improvement and SPC	• Shewart control charts • Other types of control charts • Control chart interpretation	• FMEA overview • 8D Problem solving overview • Out-of-control action plan
Dates:	03 June 2019 08:00 – 12:00	04 June 2019 08:00 – 12:00	05 June 2019 08:00 – 12:00
Venue:	Training Room 8	Training Room 8	Training Room 8
Facilitator	Quality Engineer	Quality Engineer Process Engineer	Quality Engineer Process Engineer

Table 19 illustrates the competency of all the operators and analytical chemists within the case study environment. This ties in with the MSA as competency, relative to the operating of the process and the measuring of the characteristics of all the products and in-process samples are essential when attempting to minimise variation.

The table below serves as a summary compiled from the baseline report in Section 5.8. The inclusion of this table is to signify the attempt at including the basics of SPC into the annual training regime of the organisation. Not only is this beneficial for the immediate implementation of SPC, but it also supports the aim to implement a sustainable programme, which is integrated into the standard operating procedures of the organisation.

Table 19: List of competency certificates for employees at work stations

Process	Validation/Capability/Verification/Report	Record	Remark
OP10	Competency of Operator	Certificate of Competency of Operator 41 K	Exp. Date : Aug 2019
OP20	Competency of Operator	Certificate of Competency of K1	Exp. Date : Aug 2019
OP30	Competency of Operator	Certificate of Competency of K1	Exp. Date : Aug 2019
OP40	Competency of Operator	Certificate of Competency of K1	Exp. Date : Aug 2019
OP50	Competency of Operator	Certificate of Competency of K1	Exp. Date : Aug 2019
OP60	Competency of Operator	Certificate of Competency of K2	Exp. Date : Nov 2019
	Competency of Lab Analyst	Certificate of Competency of Analyst Q1	Exp. Date : May 2019
OP70	Competency of Operator	Certificate of Competency of K2	Exp. Date : Oct 2019
	Competency of Lab Analyst	Certificate of Competency of Analyst Q1	Exp. Date : Nov 2019
OP80	Competency of Operator	Certificate of Competency of K2	Exp. Date : Nov 2019
	Competency of Lab Analyst	Certificate of Competency of Analyst Q1	Exp. Date : Nov 2019
OP90	Competency of Operator	Certificate of Competency of K2	Exp. Date : Nov 2019
	Competency of Lab Analyst	Certificate of Competency of Analyst Q1	Exp. Date : Nov 2019
Testing Method	Qualified Laboratory Method	Lab Method 401	Qualified

Once the employees are deemed skilled and competent, the essential step of process prioritisation follows. This step is critical as failure to apply the new-found skills and abilities to the appropriate processes will deem the attempt futile. The prioritisation of processes is explained in an action research and step-by-step methodology.

5.5. Process prioritisation

The metric identification process for SPC is a key aspect of this research project. As mentioned in the literature review, most implementation frameworks focus on the organisational success factors for the implementation of SPC. The challenge is encountered when pursuing an appropriate methodology for the implementation of SPC, and even more so in the chemical manufacturing environment as most methodologies focus on the machining and automotive industry. The prioritisation of the process, the input characteristics and the output characteristics are identified using the methods highlighted in Figure 28. The detailed procedure followed is discussed and illustrated in the next chapter.

5.5.1. Step 1 – Process prioritisation using Pareto analysis

The pilot facility was identified by performing a Pareto analysis on the defect data collected at the case study environment. The results are illustrated in Figure 34 and Figure 35. The results indicate that 93% of material defects for 2017 and 78% of defects for 2018 were identified at facility α. Facility α is identified as the preferred facility to implement the pilot SPC project. The subsequent exercise will concentrate on identifying the input and output variables of the process.

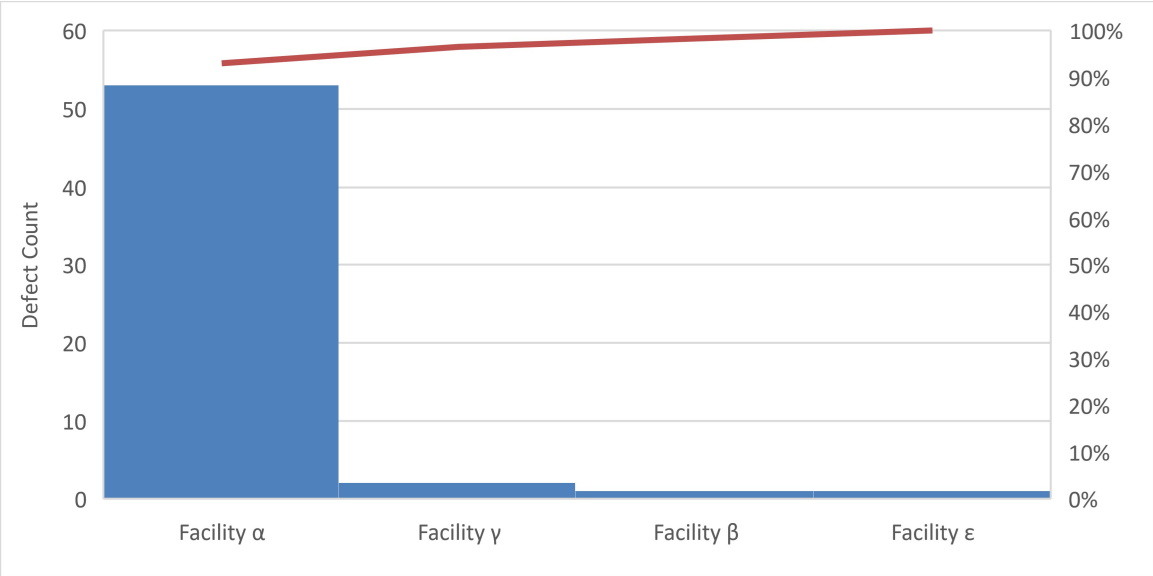


Figure 34: Pareto analysis of defect frequency per facility in 2017

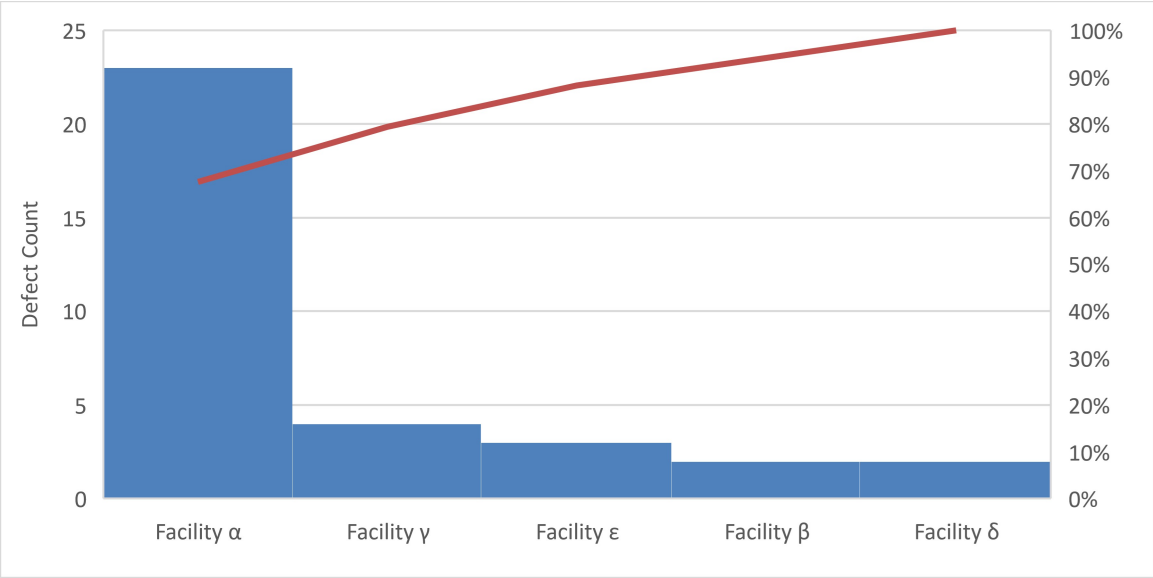


Figure 35: Pareto Analysis of defect Frequency per facility in 2018

Following the identification of the target facility, the next step was to identify the output characteristics for which the process proves to be the least capable. A capability study was performed on the facility by assessing the capability of the final product characteristics relative to the product specification.

5.5.2. Step 2 – Determination of critical to quality output characteristic (Y-Metric)

As mentioned in the preceding sections, the capability study on the process will identify the least capable output characteristics. It is generally accepted that a process with a capability index ≤ 1 is minimally capable and processes with capability index of ≥1.33 have a good capability. Table 2 displays the capability index requirements in more detail. The required indices are used when sanctioning the capability of a process. The objective is to improve the process performance, therefore the characteristics with the poorest capabilities which are ≤ 1 will automatically form part of the SPC study.

5.5.2.1. Prerequisite: Process capability studies

Prior to the evaluation of capability the requirements below should be fulfilled to ensure the most accurate assessment.

- All measuring instruments, gauges and equipment used shall be calibrated prior to manufacture of evaluation batches.
- Measuring equipment utilised shall be capable of providing results to ensure that the process capability and centring can be effectively analysed.
- Statistical process control data is to be utilised.
- The process shall be analysed for capability and centring where two-sided specifications exist and for capability where only one-sided specifications exist.
- The samples for statistical process capability measurement shall be run without any process adjustment and under supervision.

- Only approved suppliers for the supply of raw materials shall be used.

Upon fulfilling the above requirements, the evaluation batches can be manufactured for data collection.

5.5.2.2. Process capability sentencing criteria

The available data will be statistically analysed to determine the process capability (C_p) and centring (C_{pk}) of the process. The process capability index is evaluated by comparing the collected measurements with the specification tolerance. The following formulae were used:

Table 20: Process capability formulae

Type of specification	Formula For PCI
2-sided specification(C_p)	(USL – LSL)/6σ
Only an upper specification limit(CPU)	(USL- $\overline{X}$)/3σ
Only a lower specification limit(CPL)	($\overline{X}$ -LSL)/3σ

Source: (AIAG, 2005; Montgomery, 2009; Montgomery & Runger, 2007)

Process with 2-sided specifications will be evaluated for centring. A process is perfectly centred when the $C_p = C_{pk}$ (Sharma & Kharub, 2014b).The C_{pk} is calculated as the minimum of either CPU or CPL. Table 21 illustrates the classification modes used in the case study environment. The process will be seen as capable if it conforms to the requirement illustrated below. Each product characteristic is classified with a specific classification based on the criticality to its function within the process environment.

Table 21: Capability index requirements adapted from Sharma and Kharub (2014a)

Classification of the characteristic	Process capability and centring index requirement
Critical	≥1.66
Major A	≥1.33
Major B	≥1.11
Minor	≥1.00

It is mentioned above that the capability index of each characteristic is determined when performing a FMECA on the product. The capability indices are tied to the failure modes, effects and criticality analysis. The capability index for each characteristic used in the case study environment was derived from the FMECA using internal procedures, where the severity was used to classify the characteristics. The relevance of the linking can be supported as it is utilised in the case study environment with similar procedures found in literature used by Ford (2011), Montgomery (2009) and the USA DOD (1980). Table 22 contains the

information used to classify the characteristics using the FMECA, which then determines the capability index. Further information is provided in section 2.8.1.

Table 22: Table of indices for severity and product characteristic classification using FMEA

Effect	Severity of effect on product, process or customer	Ranking	Classification	Process Capability and Centring Index Requirement (C_p and C_{PK})	Estimated allowed occurrences based on classification (DPMO)
Hazardous without warning	May endanger operator or equipment without warning	10	Critical	≥1.66	0.34
Hazardous with warning	May endanger operator or equipment with warning	9	Critical	≥1.66	0.34
Very High	Loss of primary function or 100% of product needs to scrapped and compromising safety of operator or equipment	8	Major A	≥1.33	96
High	Degradation of primary function, portion of products may need to be scrapped/ deviation from process and may lead to possible equipment damage	7	Major A	≥1.33	96
Moderate	Loss of secondary function and 100% of product needs to be reworked or may cause minor damage to equipment.	6	Major B	≥1.11	967
Low	Reduced efficiency and portion of product needs to be segregated and reworked.	5	Major B	≥1.11	967
Very Low	Product non-conformance with significant degradation of performance or 100% of product requires in-process rework	4	Minor	≥1.00	2700
Minor	Product non-conformance with some degradation of performance or portion of product requires in-process rework.	3	Minor	≥1.00	2700
Very Minor	Product non-conformance with minor inconvenience to process, operation and operator	2	Minot	≥1.00	2700
None	No effect	1	Minor	≥1.00	2700

Source: Adapted from (Ford, 2011; Kulkarni & Shrivastava, 2013)

5.5.2.3. Summarized results and conclusion process α

Table 23 illustrates the summarised results of the capability study performed on the process in order to determine the least capable output characteristic. The main results highlights Y_1 with a C_p value of 0.75 and Y_2 a Cp of 0.74, which are both below 1 and also the two lowest values. Therefore these characteristics are chosen to be monitored using SPC.

Table 23: Process capability and centring results for facility α

Characteristic	Calculated Cp	Calculated Cp_k	Comments
Y_1	0.75	0.57	Does not conform to the process capability and centring requirements.
Y_2	0.74	0.70	Does not conform to the process capability and centring requirements.
Y_3	1.23	1.07	Conforms to the Process Capability Requirements.
Y_4	N/A	N/A	There is no variation in the data but all results conform to the specification
Y_5	2.62	2.62	Conforms to the Process Capability Requirements.

Process Capability of Y_1

The distribution plot in Figure 36 illustrates the results obtained for the capability study for Y_1. The process capability assessment shows that the process is not capable and needs to be improved to reduce the number of defects per million opportunities. SPC was used to improve the performance of this parameter.

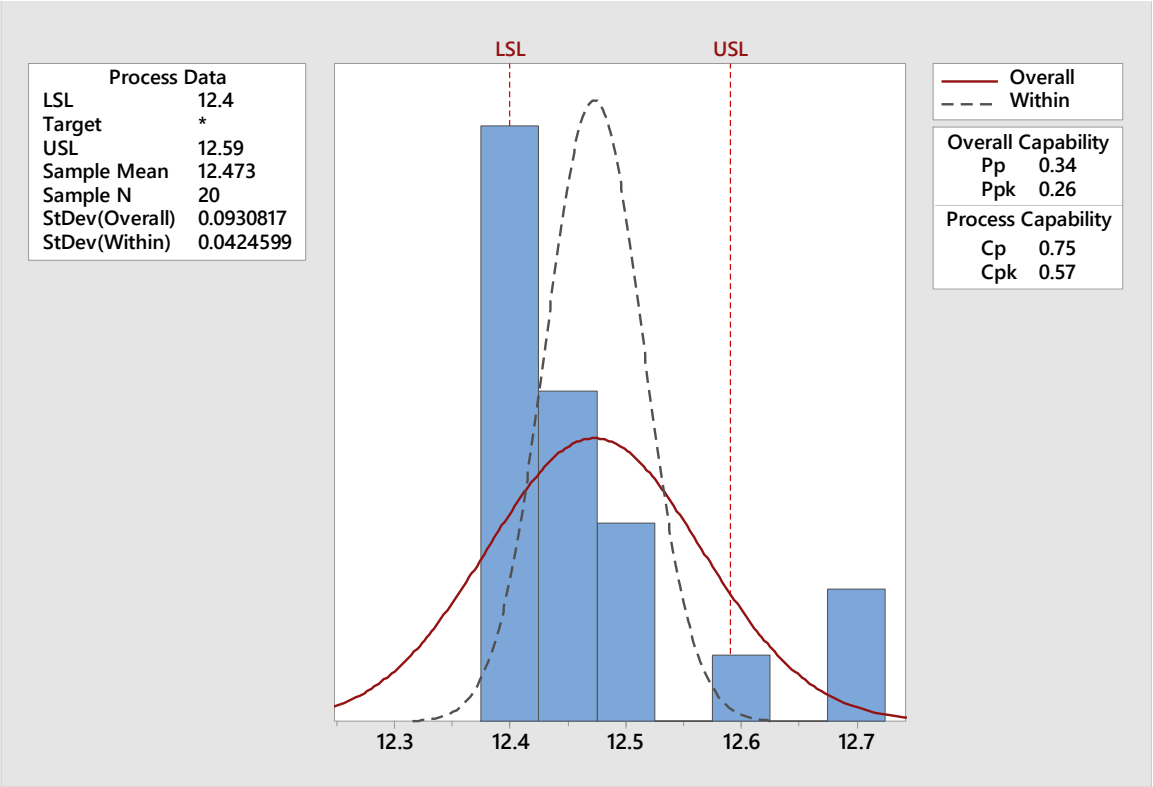


Figure 36: Distribution plot for results of Y_1 using Minitab®

Process capability of Y_2

The distribution plot in Figure 37 illustrates the results obtained for the capability study for Y_2 of facility α. The process capability assessment shows that the process is not capable and needs to be improved to reduce the number of defects per million opportunities. SPC was used to improve the performance of this parameter. This parameter will be the second Y metric and illustrated as Y_2 in all further discussions.

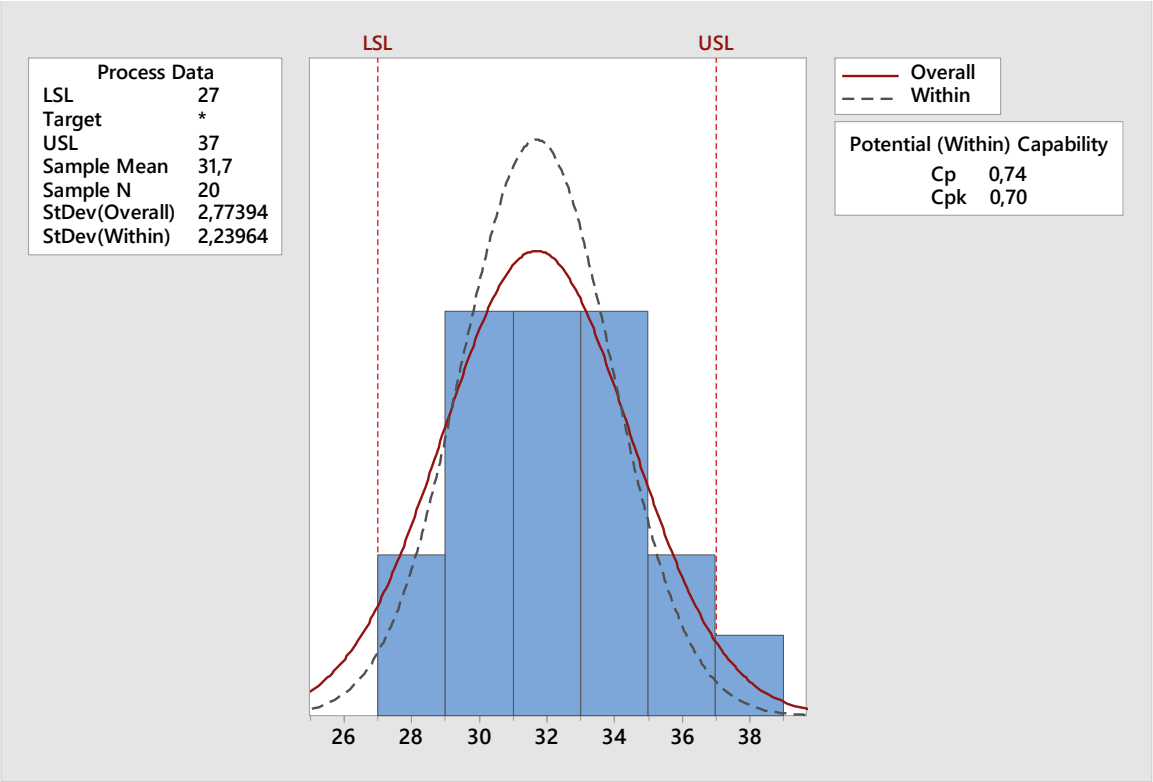


Figure 37: Distribution plot for results of Y_2 using Minitab®

Process capability of Y_3

The distribution plot in Figure 38 illustrates the results obtained for the capability study for the parameter Y_3. The process capability assessment shows that the process is capable but, not perfectly centred as there is a deviation between the C_p and C_{pk} indices.

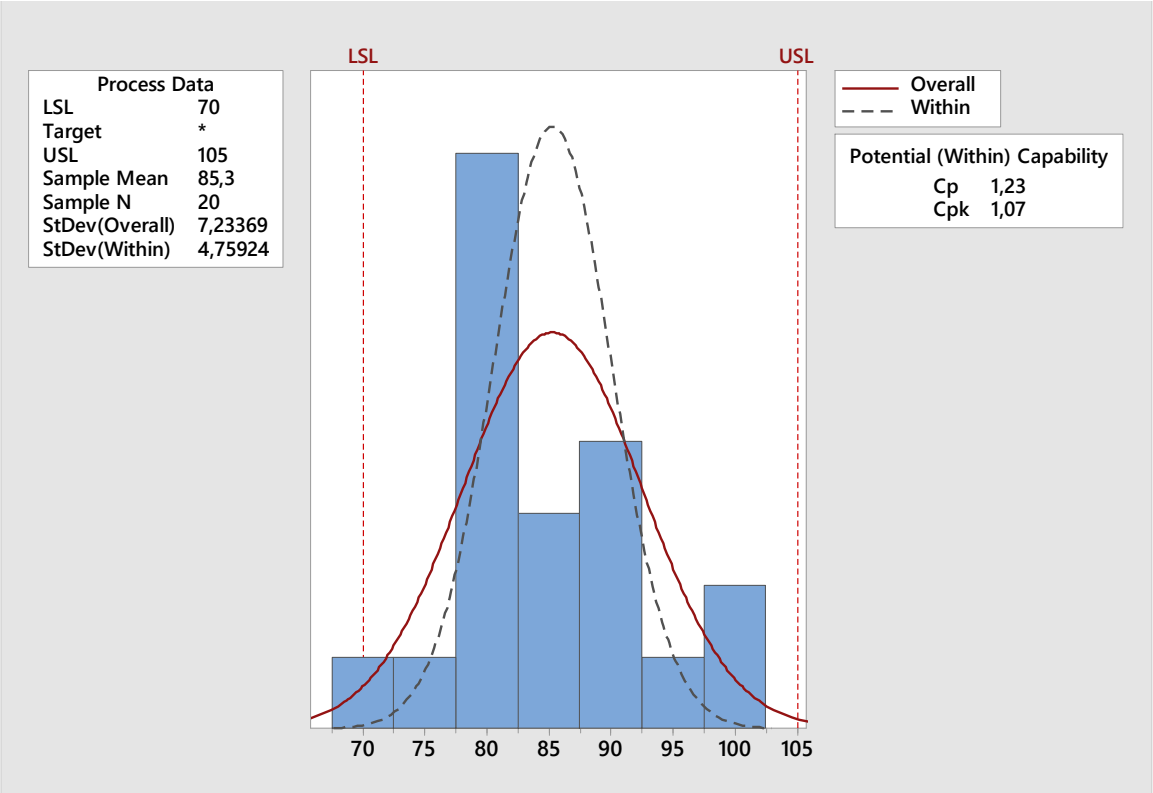


Figure 38: Distribution plot for results of Y_3 using Minitab®

Process capability of Y_5

The distribution plot in Figure 39 illustrates the results obtained for the capability study for Y_5. The process capability assessment shows that the process is capable, but not perfectly centred as there is a deviation between the C_p and C_{pk} indices.

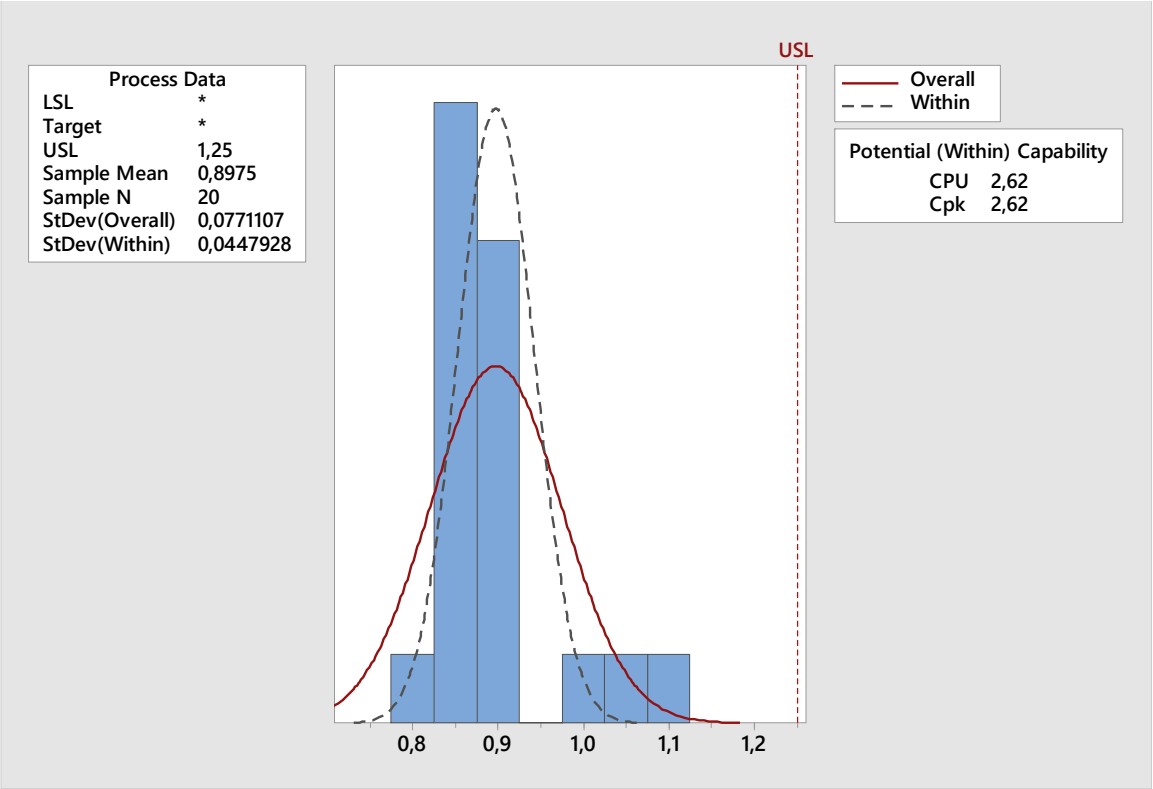


Figure 39: Distribution plot for results of Y_5 using Minitab®

Defect statistics for 2017 and 2018

The statistics when comparing the various sources of the defects for 2017 and 2018 indicate that for 2017, 42% of the defects were due to Y_2 and 57% due to Y_5 failures. During the 2018 production year 78% of the defects were due to Y_2 failures. The reduction in Y_5 failures can be accounted for by a fundamental process change which does not form part of the scope of this study.

5.5.2.4. Conclusion

Y_1 and Y_2 of the manufacturing process do not comply with the process capability requirements and need to be improved. All the other characteristics conform to the process capability requirements.

The capability results coupled with the defect statistics indicate that the Y_2 and the Y_1 content are the output characteristic which require significant improvement. The Y_2 and the Y_1 will undergo further exploration as part of the process prioritisation.

5.5.3. Step 3 – Determination of input characteristic (X - Metric)

The next step is used to identify the critical input characteristics which will be monitored and controlled to reduce the variation on the output characteristics. Therefore, identifying causal relationships between input and output characteristics. This section is critical to the validation, as the 'how to' in SPC implementation for process prioritisation available in published literature lacked significant detail. This section highlights the

approach presented and applied by the author in the case study environment, in support of validating the framework, and details the steps followed to identify the CTQ input characteristics. Regression analysis is applied to model and estimate the statistical significance of the relationships between the independent input characteristics and the output characteristics.

For both characteristics identified in the previous section, a cause and effect diagram was used to identify and eliminate characteristics which, theoretically, should have no effect on the output characteristics. The resulting characteristics were then evaluated using regression analysis to identify statistically significant causal relationships.

For the regression analysis, the following points are highlighted as aspects which can be improved and should be considered when evaluating the outputs of the regression analysis:

- The sample size of the dataset should be large enough to represent a very precise estimate of the strength of the relationship.
- Ensure that the dataset is clear of assignable cause variation as this will influence the results.
- The size of the dataset will influence the accuracy and sensitivity of the p-value.
- Ensure that the sample adequately represents the range of X values for which you require monitoring and control.

5.5.3.1. Y_2 – Summary of results

As mentioned above, Figure 40 illustrates the input characteristics with possible causal relationship with the Y characteristic. These characteristics were analysed using regression analysis. Minitab® statistical software was used to process the data using the regression analysis function. The calculation is performed by evaluating the statistical significance of the causal relationship between the two evaluated characteristics with the p-value used to express the significance. A $p \leq 0.05$ indicates a statistically significant relationship. The output of Minitab® also provides the Pearson correlation which indicates a positive or negative correlation between the two parameters.

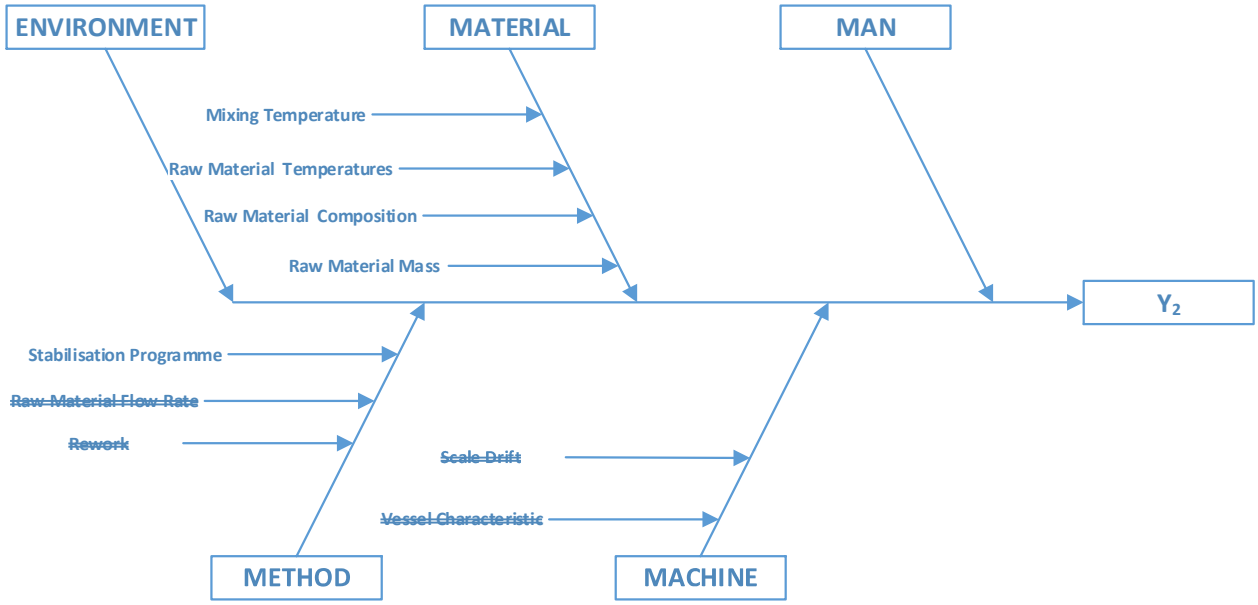


Figure 40: Cause and effect analysis (Ishikawa) for output characteristics for Y_2

Upon completing the regression analysis, it was concluded that the results returned using the datasets indicated no statistically significant causal relationships between any of the input characteristics and Y_2. Due to the complexity of the manufacturing process, elements exist further upstream which could possibly have an effect on the process for which quantitative data is not available. The most definite test for causal relationships is design of experiments (DOE). This allows the ability to manipulate input characteristics experimentally and assess the effect on the output characteristics. This method is advised, but can be costly. However, the results obtained from the multivariate analysis is accepted and is also the most cost-effective method of highlighting causal relationships. Therefore, the scope of the research does not allow for design of experiments which would be the next layer of process prioritisation as this would provide the most definite causal relationship. The regression analysis step is continued to evaluate the causal relationships for the next characteristic. For practical and illustrative purposes the author aims to identify at least one relationship between an input and an output characteristic. This relationship will be monitored using SPC.

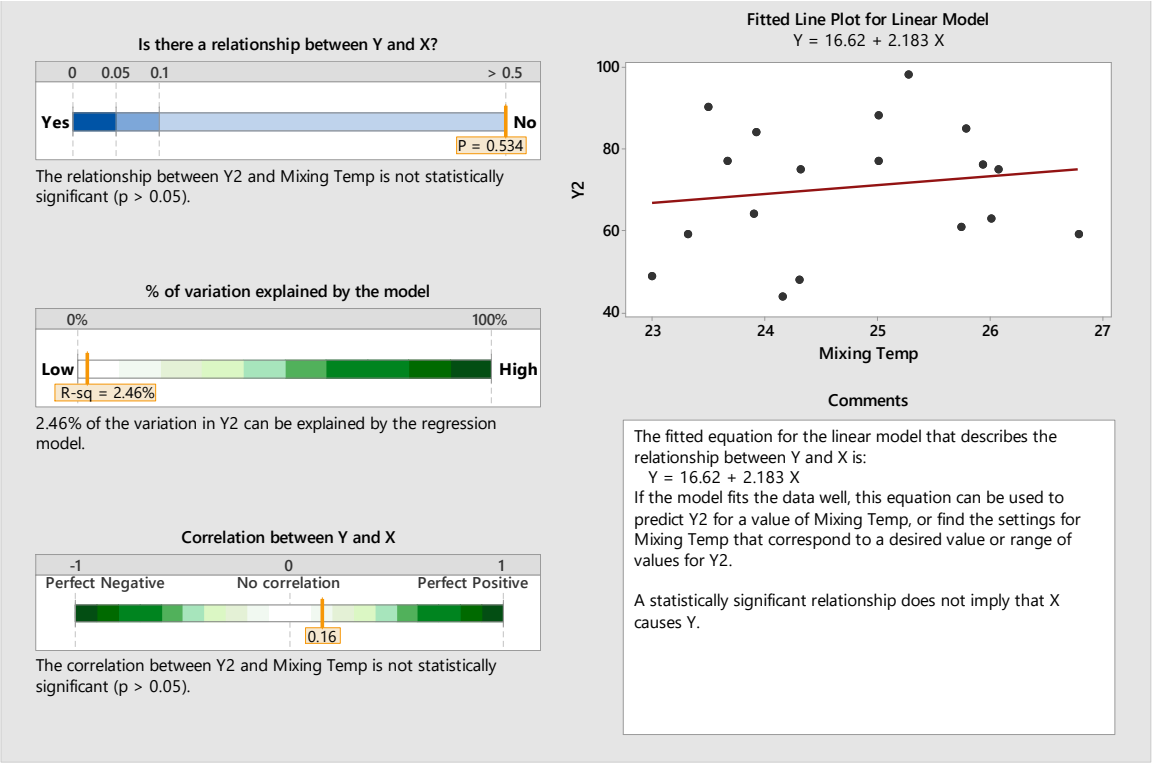


Figure 41: Regression analysis summary report for Y_2 vs mixing temperature using Minitab®

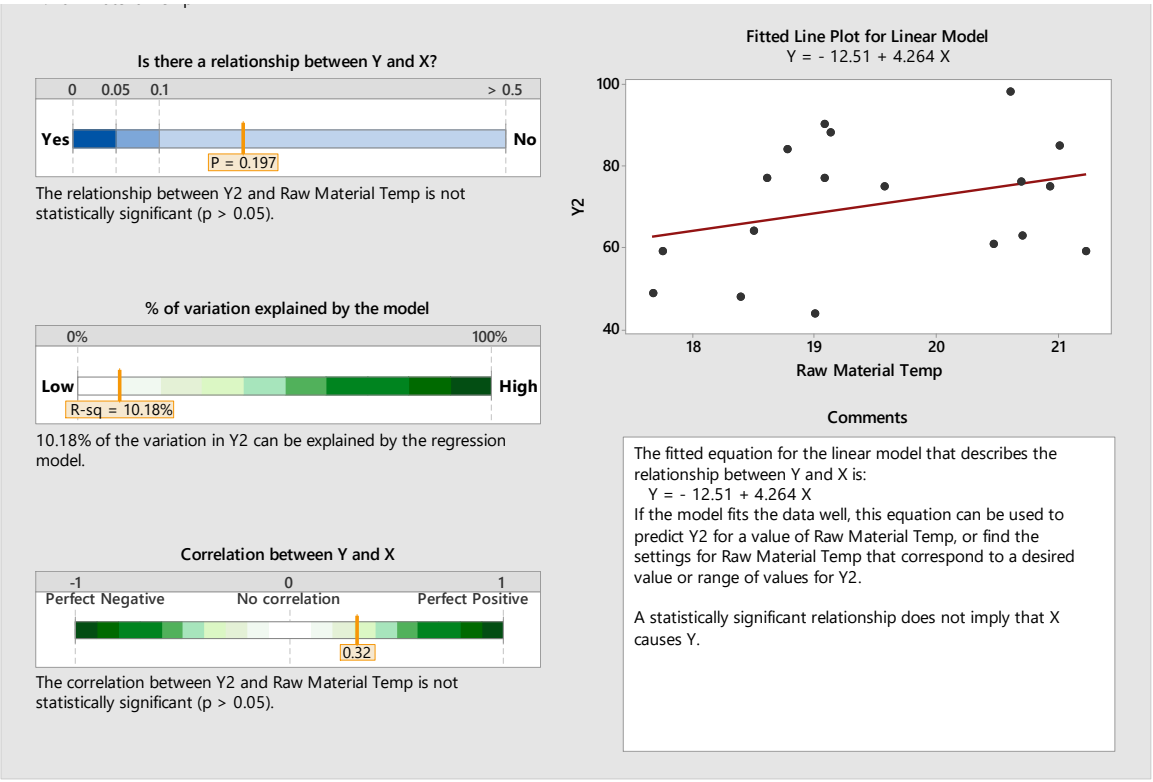


Figure 42: Regression analysis summary report for Y_2 vs raw material temperature using Minitab®

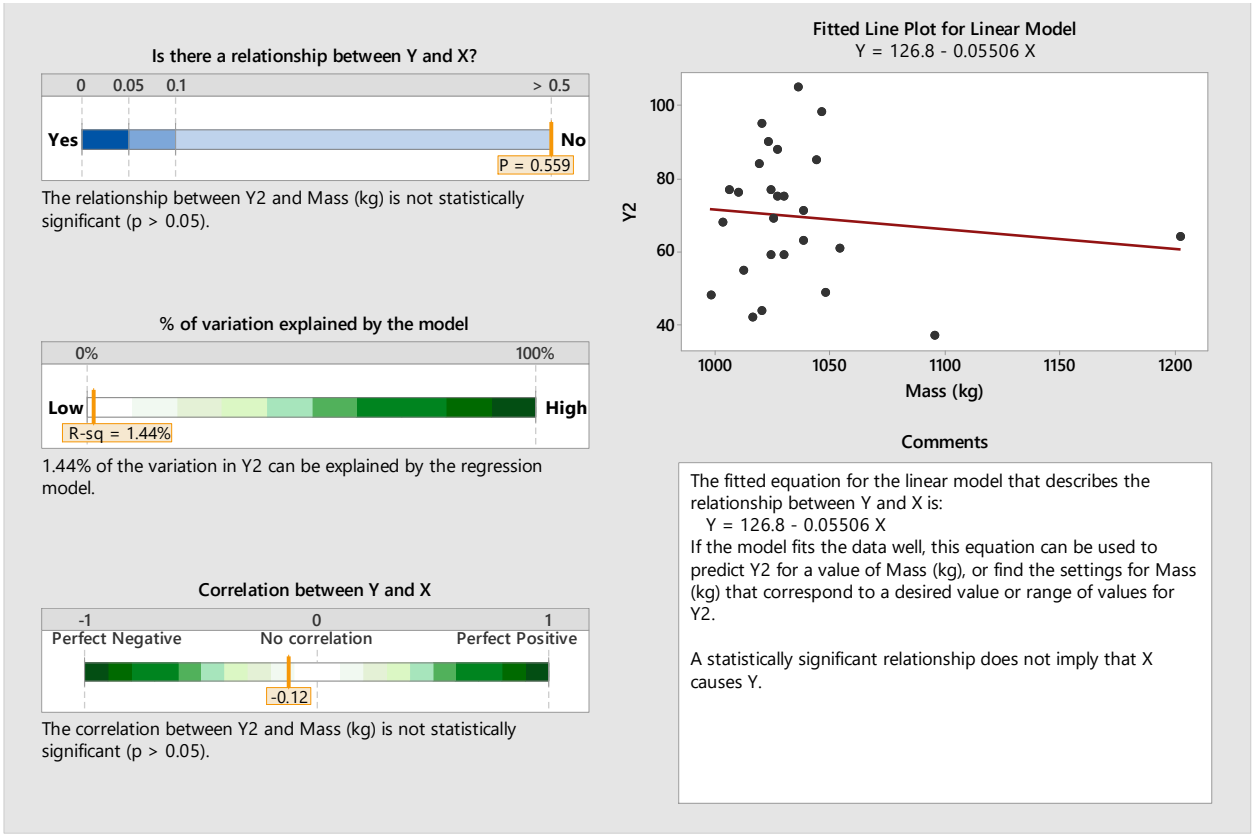


Figure 43: Regression analysis summary for Y_2 vs raw material mass using Minitab®

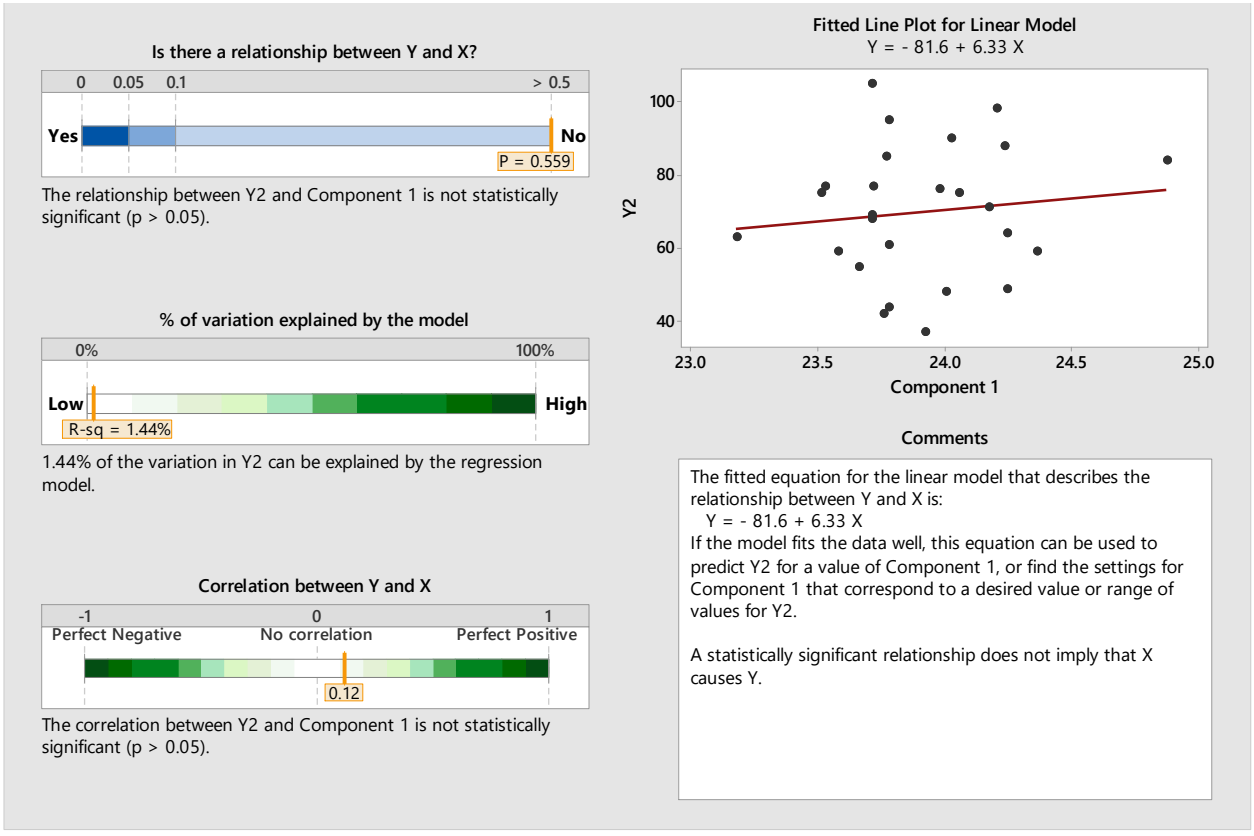


Figure 44: Regression analysis summary for Y_2 vs raw material component 1 Minitab®

5.5.3.2. Y_1 – Summary of results

Similarly to Y_2, the cause and effect diagram (Figure 45) was used to evaluate all possible input characteristics and their potential effect on Y_1. In the previous evaluation for Y_2, the temperature of the raw material was eliminated as a potential cause. The manufactured material is produced in different grades of Y_1 with the lower grades more significantly affected by their raw materials than process parameters. Therefore, using the cause and effect diagram, the raw material composition was identified and evaluated using regression analysis to establish which component has the most significant effect on Y_1.

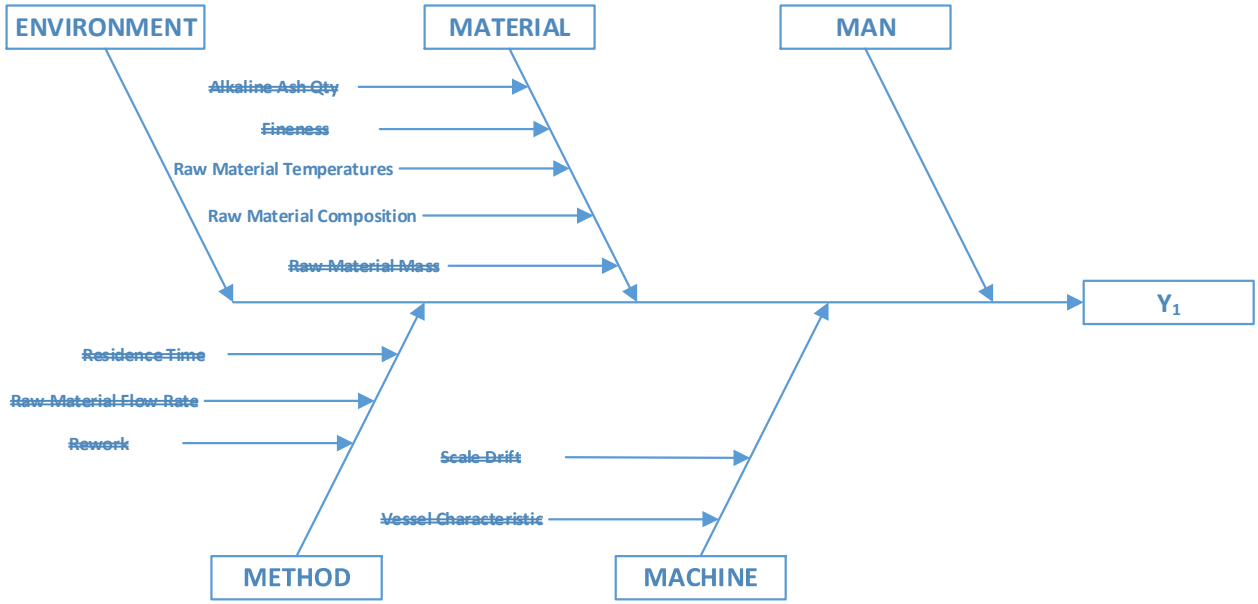


Figure 45: Cause and effect analysis (Ishikawa) for output characteristic for Y_1

The raw material and reactor temperatures for the higher grade products were evaluated with visible trends, but no statistically significant causal relationships, as illustrated in Figure 46 and Figure 47.

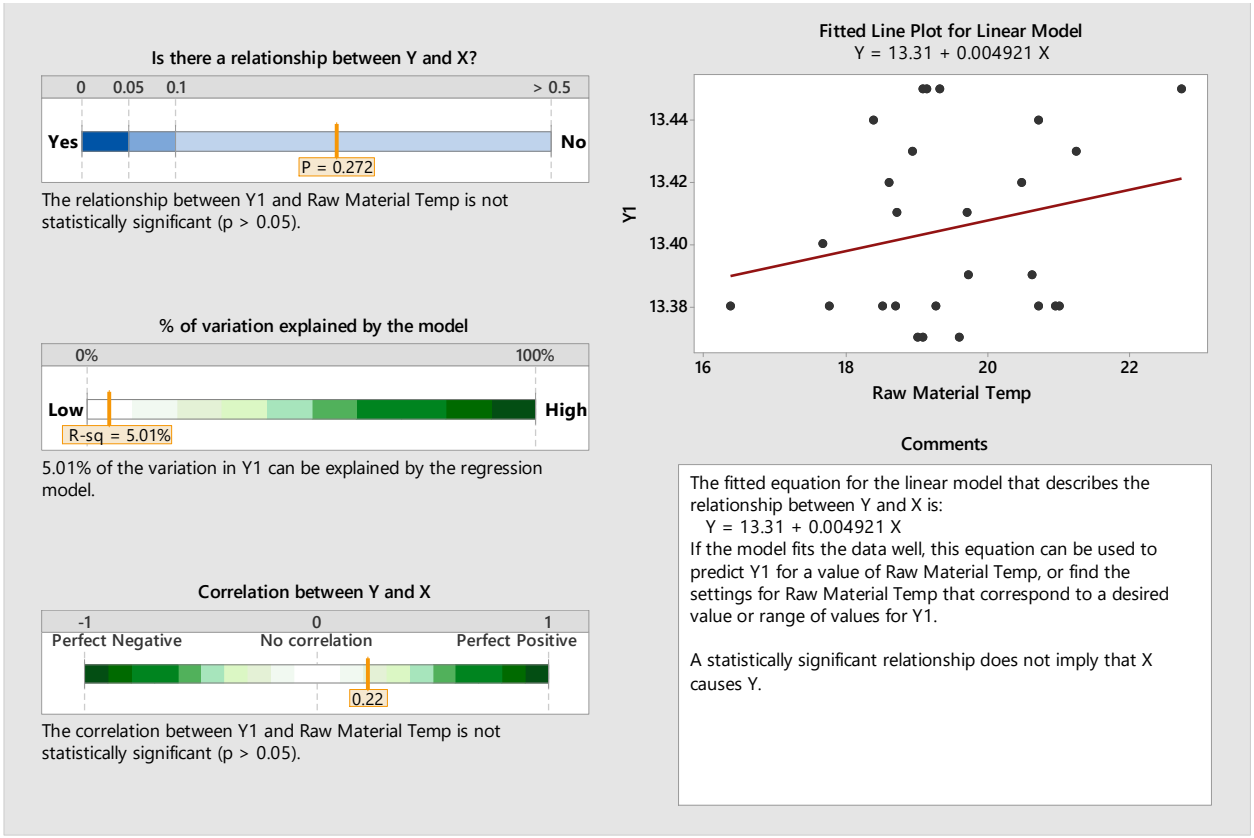
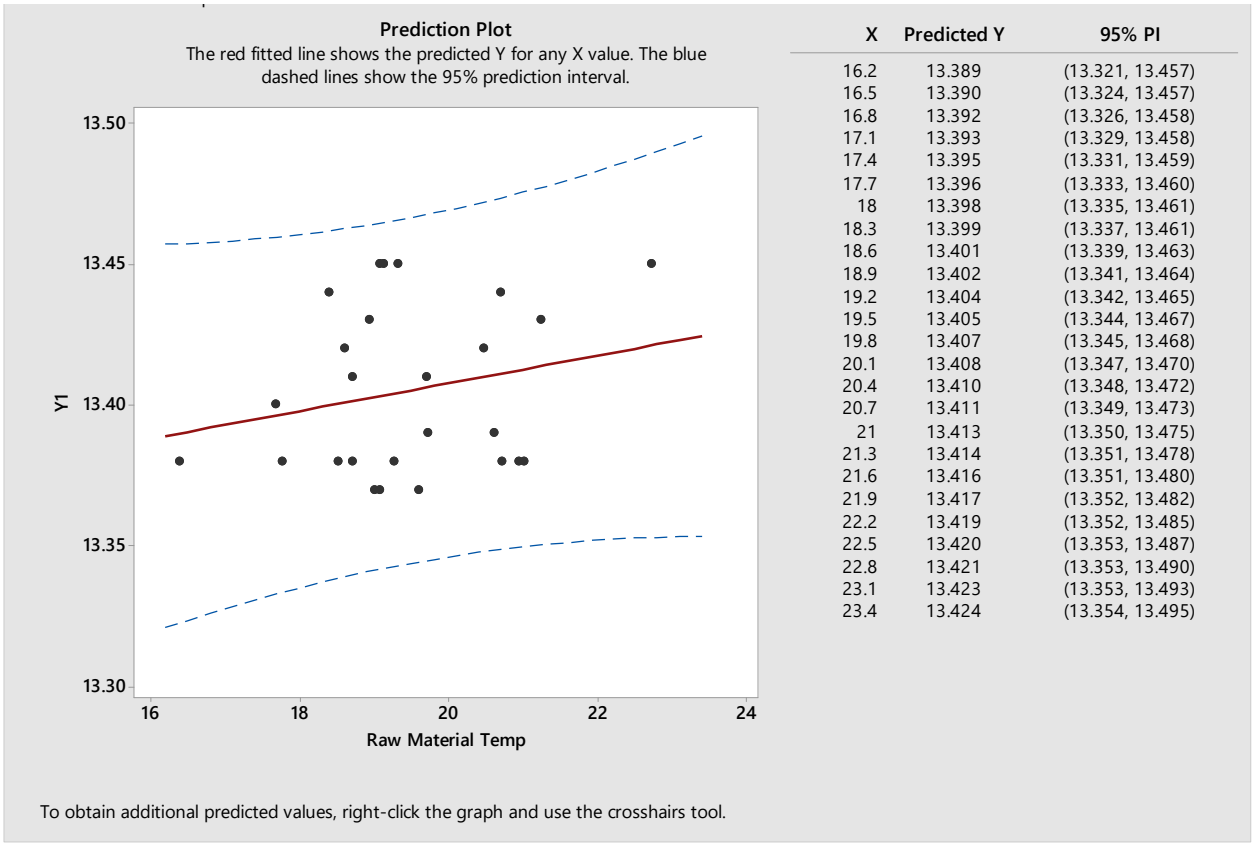


Figure 46: Regression analysis summary for Y_1 vs raw material temperature using Minitab®



X	Predicted Y	95% PI
16.2	13.389	(13.321, 13.457)
16.5	13.390	(13.324, 13.457)
16.8	13.392	(13.326, 13.458)
17.1	13.393	(13.329, 13.458)
17.4	13.395	(13.331, 13.459)
17.7	13.396	(13.333, 13.460)
18	13.398	(13.335, 13.461)
18.3	13.399	(13.337, 13.461)
18.6	13.401	(13.339, 13.463)
18.9	13.402	(13.341, 13.464)
19.2	13.404	(13.342, 13.465)
19.5	13.405	(13.344, 13.467)
19.8	13.407	(13.345, 13.468)
20.1	13.408	(13.347, 13.470)
20.4	13.410	(13.348, 13.472)
20.7	13.411	(13.349, 13.473)
21	13.413	(13.350, 13.475)
21.3	13.414	(13.351, 13.478)
21.6	13.416	(13.351, 13.480)
21.9	13.417	(13.352, 13.482)
22.2	13.419	(13.352, 13.485)
22.5	13.420	(13.353, 13.487)
22.8	13.421	(13.353, 13.490)
23.1	13.423	(13.353, 13.493)
23.4	13.424	(13.354, 13.495)

Figure 47: Prediction report for regression analysis of Y_1 vs average raw material temperature Minitab®

Figure 48 and Figure 49 illustrate the regression analysis for the raw material composition for the higher grade products. Raw material component 1 had the least causal connection as illustrated by p = 0.756 with p value of raw material component 2 equal to 0.35. The same characteristics were investigated for lower grade Y_1 as these are the products which will be manufactured in high volumes in 2019.

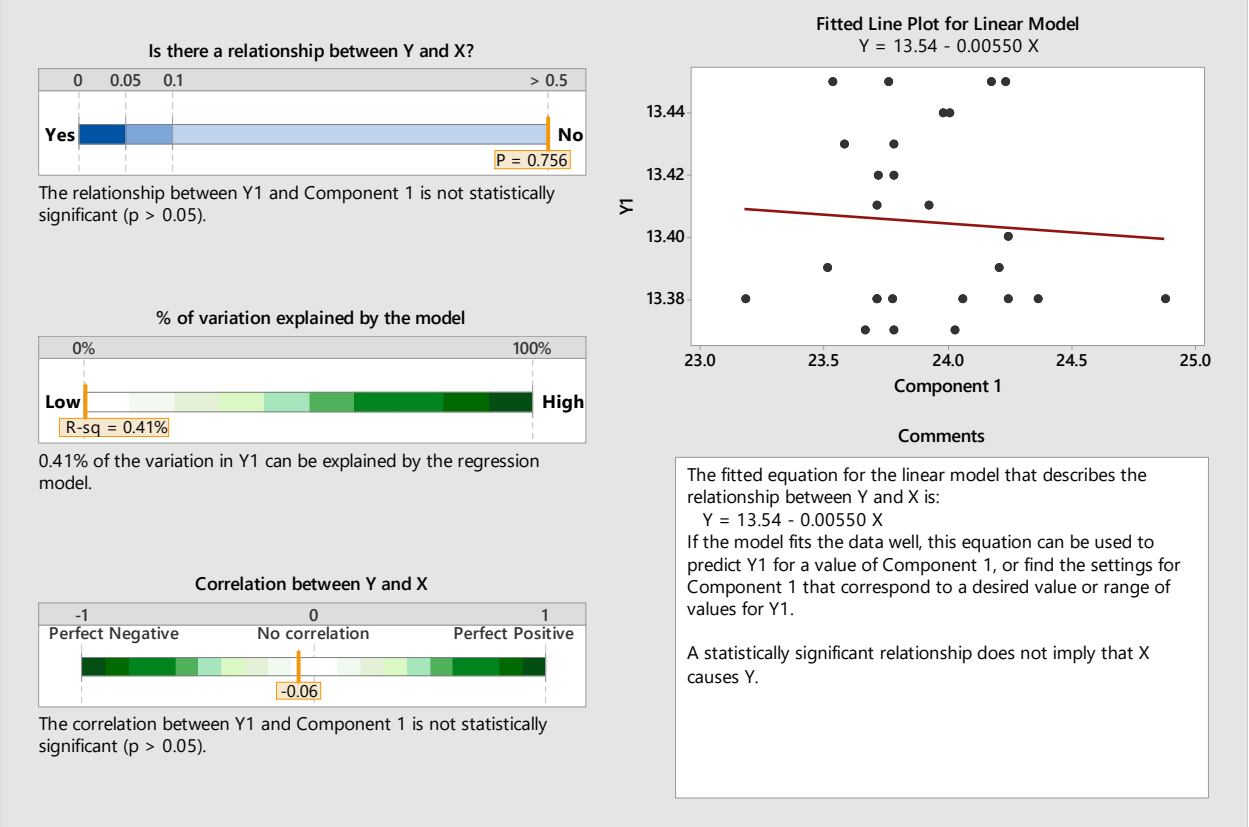


Figure 48: Summary report of regression analysis of Y_1 vs component 1 content using Minitab®

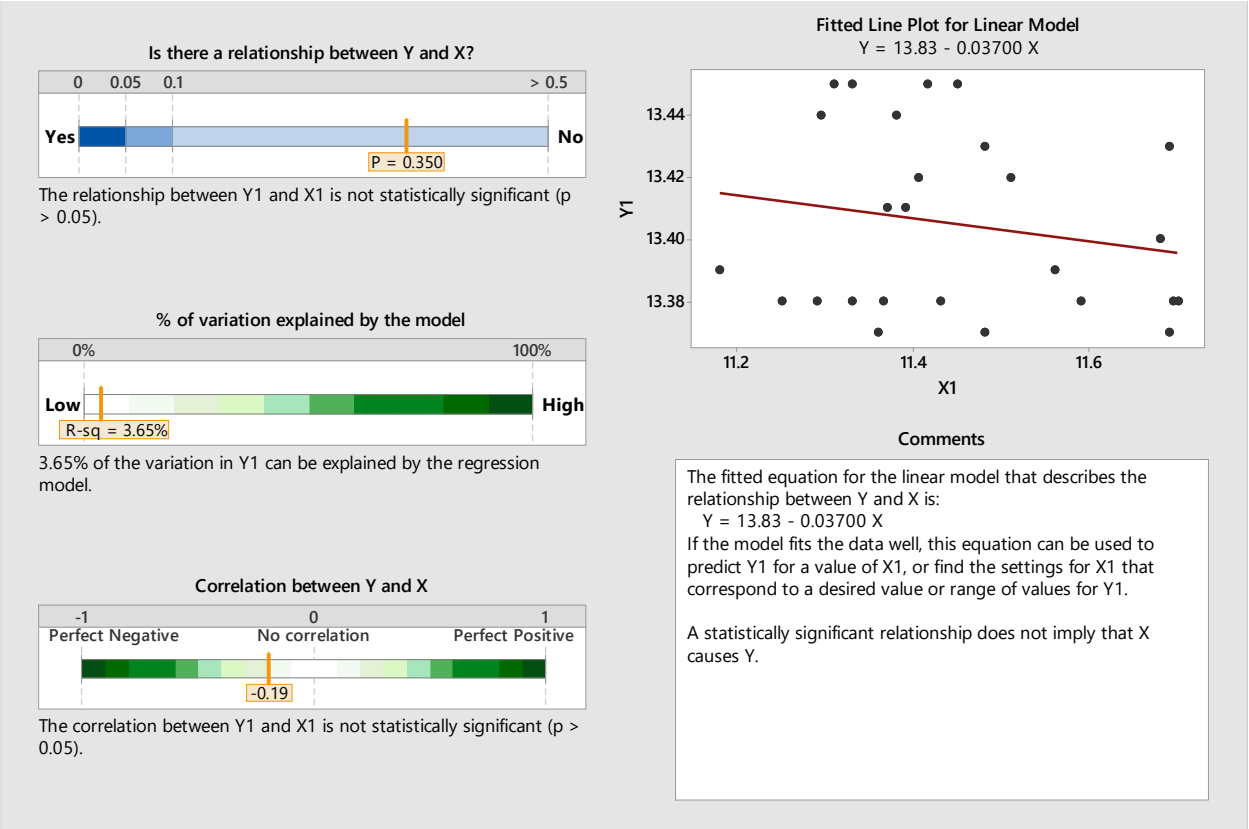


Figure 49: Summary report of regression analysis of Y_1 vs X_1 content using Minitab®

The regression analysis was performed for the lower grade Y_1 products. The component 1 content had a p = 0.35 and was subsequently removed. However, Figure 51 and Figure 52 returned positive results for X_1. The regression analysis returned a p = 0.063. However, the large residuals were removed as illustrated in Figure 52 to return the most accurate correlation between the input and output parameters.

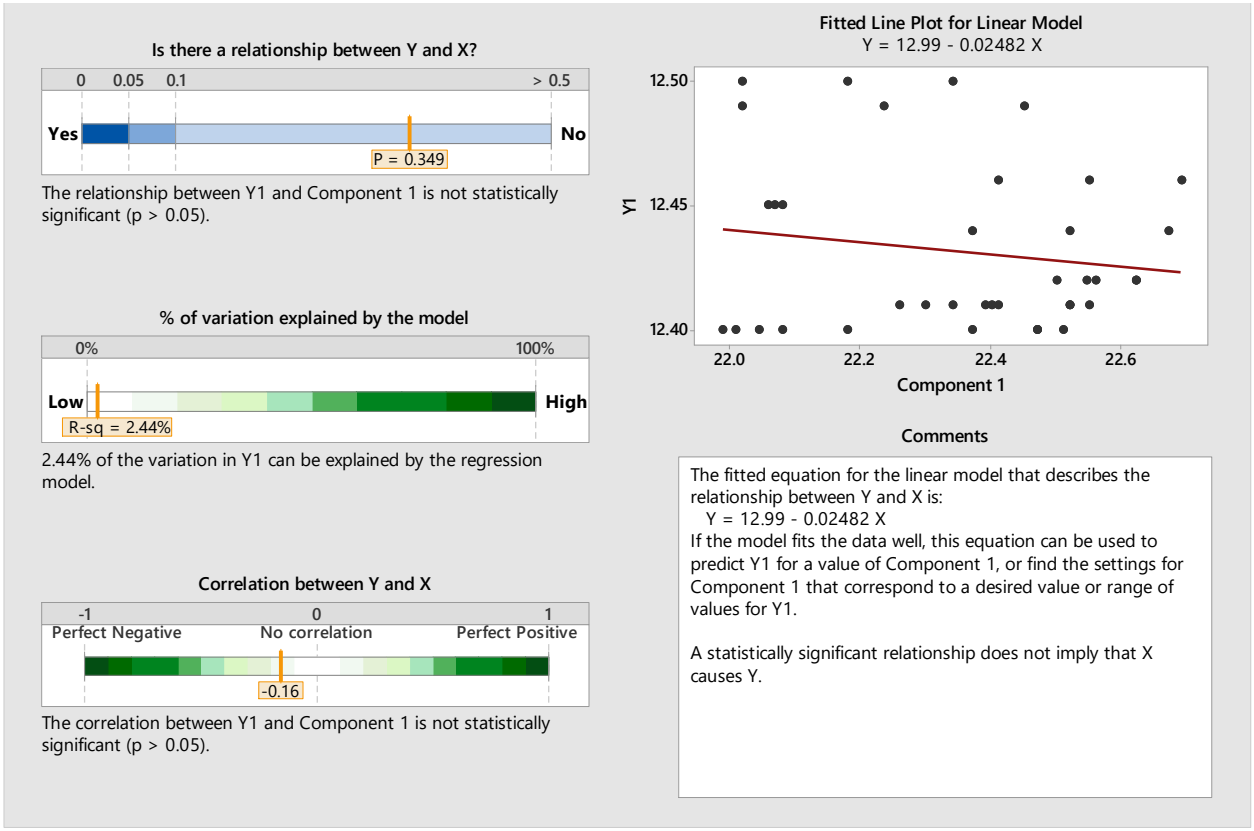


Figure 50: Summary report of regression analysis of Y_1 vs component 1 content using Minitab®

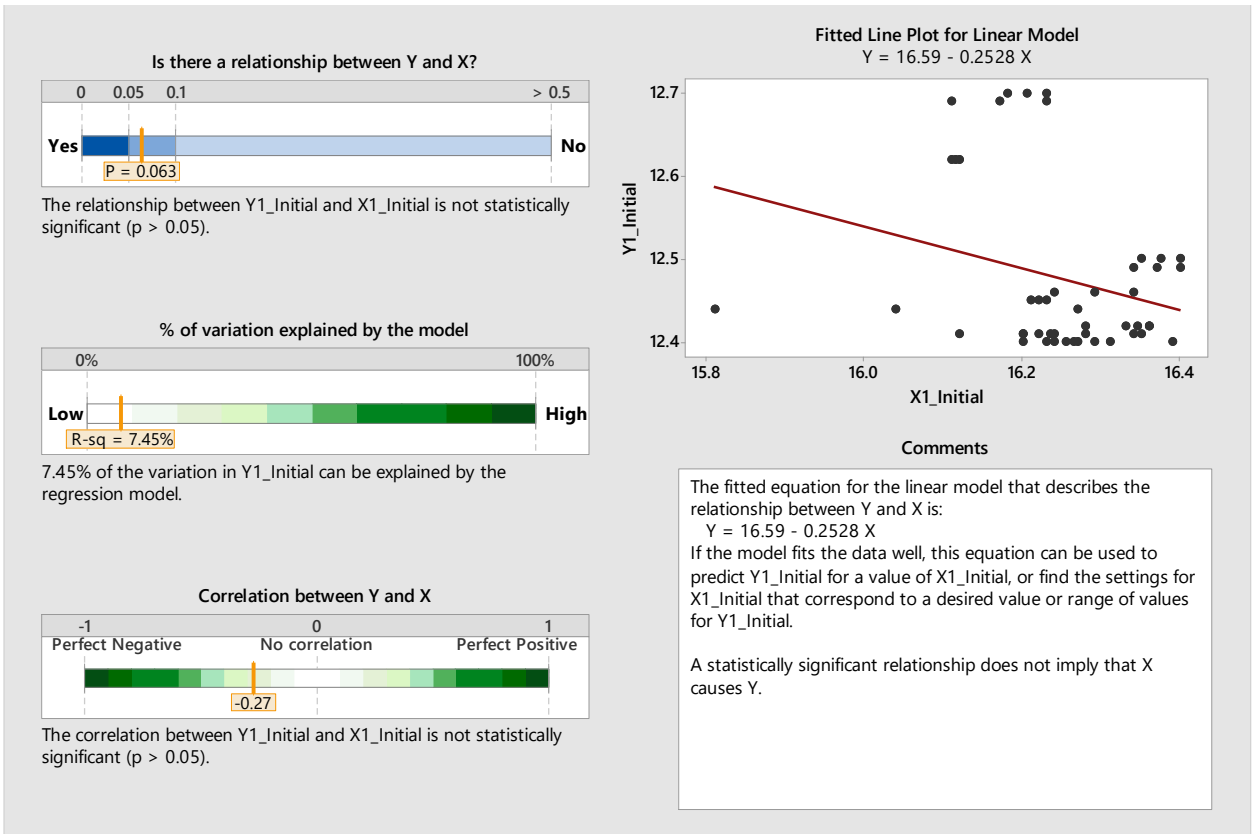
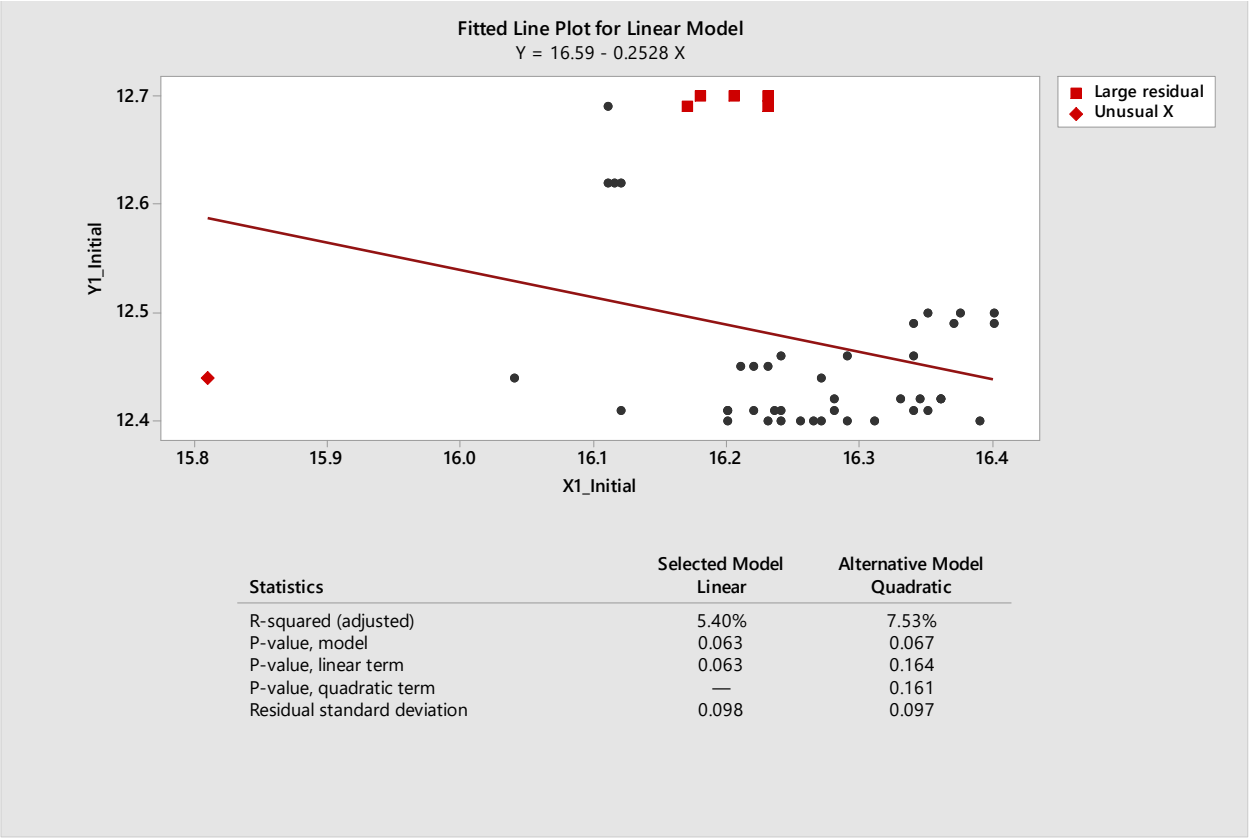


Figure 51: Summary of regression analysis for Y_1 vs X_1 – Before adjustment using Minitab®



Statistics	Selected Model Linear	Alternative Model Quadratic
R-squared (adjusted)	5.40%	7.53%
P-value, model	0.063	0.067
P-value, linear term	0.063	0.164
P-value, quadratic term	—	0.161
Residual standard deviation	0.098	0.097

Figure 52: Model selection report for Y_1 vs X_1 using Minitab®

Figure 53 and Figure 54 below illustrate a strong causal relationship between the X_1 of the raw material and the Y_1 of the product. Figure 54 illustrates a trend in the relationship between the two parameters with a maximum value for Y_1 at the lowest measurement for X_1. Furthermore, as X_1 increases from the minimum point the Y_1 decreases from maximum. The p = 0.011 demonstrates a statistically significant causal relationship.

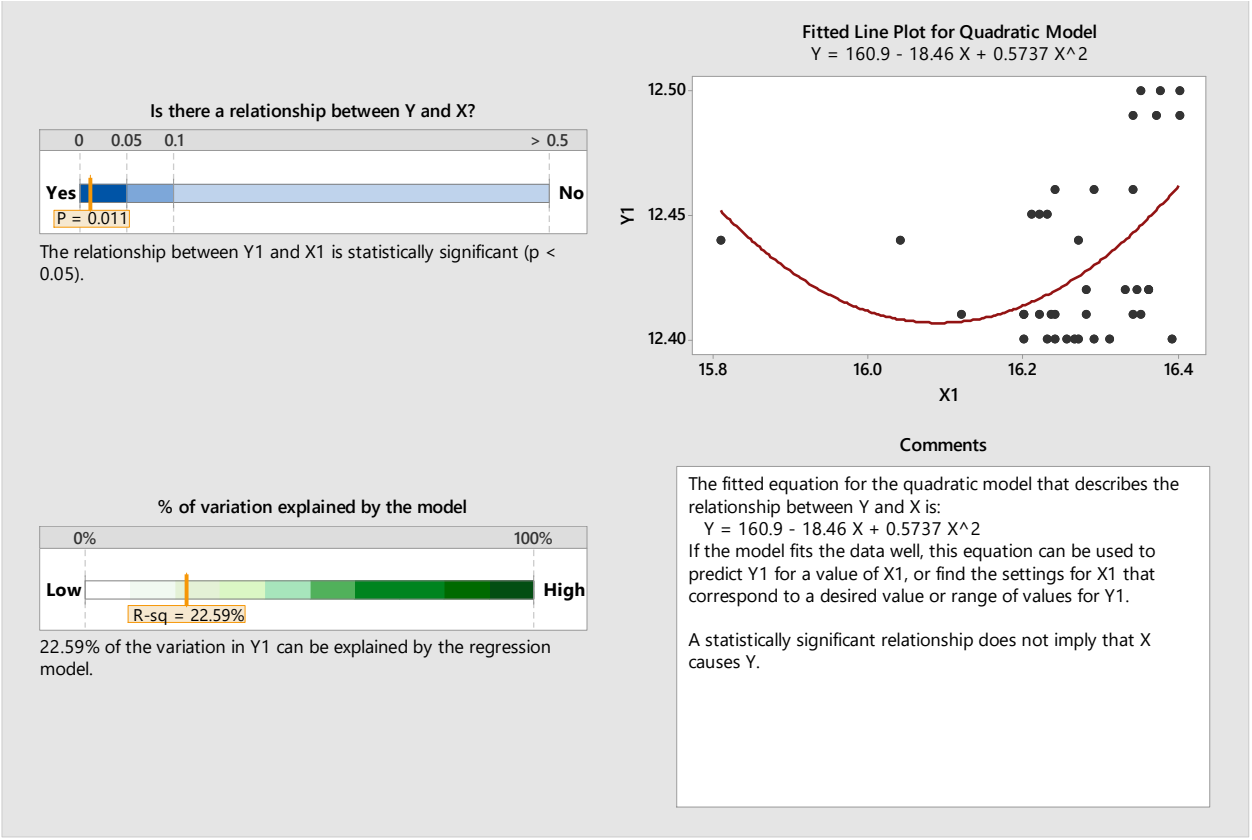
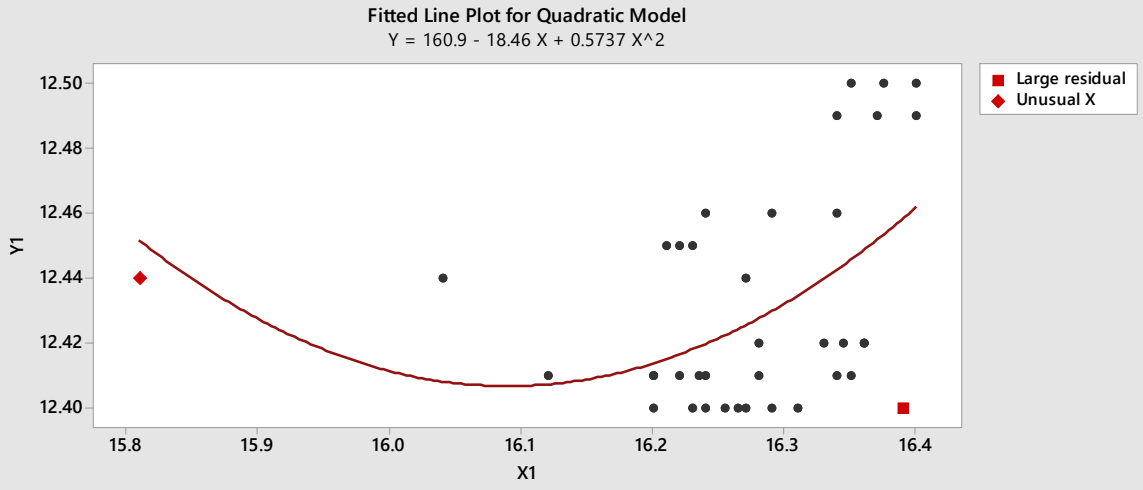


Figure 53: Summary of regression analysis for Y_1 vs X_1 using Minitab®



Statistics	Selected Model Quadratic	Alternative Model Linear
R-squared (adjusted)	18.17%	3.32%
P-value, model	0.011*	0.140
P-value, linear term	0.010*	0.140
P-value, quadratic term	0.010*	—
Residual standard deviation	0.030	0.033

** Statistically significant (p < 0.05)*

Figure 54: Prediction report of regression analysis for Y_1 vs X_1 using Minitab®

The multivariate regression analysis identified a causal relationship between Y_1 and the X_1. These characteristics will be monitored using statistical process control in order to enhance the performance of Y_1 by reducing variation in the X_1.

5.6. Measurement system analysis

The measuring system capability is performed to evaluate and identify the factors contributing towards variation when performing measurements. Therefore, MSA is used to evaluate the measurement system, which consists of the equipment and the appraiser and estimates the contribution of the measurement system to the total variation (σ_{total}).

The facilities in the case study environment are reliant on measuring instruments such as thermocouples, pressure sensors and flow meters in order to regulate and control processes at predefined set points. These instruments are used in environments which utilise cooling and heating systems and actuated valves with control loops to regulate parameters such as temperature and pressure. This, in conjunction with an analytical testing facility, constitutes the measuring, monitoring and control of process parameters and product characteristics. Accuracy and precision are important as the information returned from the measuring instruments and test methods are used to control the process and verify conformance of the products.

5.6.1. Analytical testing facility

The analytical testing facility inspects incoming raw materials, in-process samples and final products. This is performed by an analytical chemist using variations of wet chemistry and analytical instruments, to evaluate the required characteristics. The measurement system consists of the analytical methods/procedure, instruments, analysts and the environment. The following section highlights the methods implemented to assure adequate measurement system capability by performing a measurements systems analysis on the analyst and the instrument as well as qualifying laboratory methods using statistics.

The evaluation of the laboratory method and the gauge repeatability and reproducibility (GRR) will both use methods derived from measurement systems analysis. The determination of gauge variability can be performed using three (accepted) methods (AIAG, 2010; Doshi & Desai, 2019; Montgomery, 2009):

- The range method
- The average and range method
- The ANOVA method

Both the ANOVA, and the average and range method decompose the gauge study into Equation 2, illustrated in Section 2.2.

$$\sigma^2_{GRR} = \sigma^2_{reproducibility} + \sigma^2_{repeatability}$$

Where $\sigma^2_{reproducibility}$ = Appraiser Variation (AV) and $\sigma^2_{repeatability}$= Equipment Variation (AV). The range method summarises the GRR study in one metric which represent both types of measurement system variation.

The range method is used to perform the measurement system evaluation (laboratory method qualification) in this case study as it is the simplest method to use and is also the current method used for measurement system evaluation in the case study environment. The range method provides a quick approximation of gauge variability. The GRR studies for the dataset will also be performed using Minitab® Statistical Software.

5.6.1.1. Qualification of laboratory method using MSA – The range method

This section covers the evaluation of the analytical method for characteristics as identified by the author. The method evaluates the sensitivity and the repeatability of the measuring system using the range method. Seven samples of raw material were analysed in four repetitions for composition (component 1 and X_1). This instrument measures the bulk of the characteristics for facility α. The results provide adequate insight into the precision of the instrument.

Aim of statistical analyses

Measurement evaluation on the sensitivity and the repeatability of the instrument used for the determination of the raw material composition.

Summary of results

Evaluation of sensitivity

According to the available data the analytical method has adequate sensitivity to determine different levels of component 1 and component 2 of the raw material using the measuring instrument. Out-of-control points demonstrate the discriminating power of the instrument. Therefore, this establishes the ability of the instrument to distinguish between different levels of the measured characteristic for a material or product (Montgomery, 2009).

Evaluation of repeatability

According to the available data the measuring instrument has adequate repeatability to consistently determine the % m/m of component 1 and component 2 in the raw material, using the measuring instrument. This is indicated by the R-chart within statistical control.

Statistical evaluation of the results

Sensitivity analysis

The R-Chart in Figure 55 and Figure 56 illustrates a system that is within statistical control, which is an indication that the evaluation of sensitivity is reliable. This means that the analyst has no trouble making consistent measurements.

The X-Bar chart in Figure 55 and Figure 56 indicates that measurement analysis of the raw material composition using the instrument is sensitive enough to determine different levels of component 1 and component 2 content as all of them are statistically inconsistent. As mentioned above, this highlights the discriminating power of the instrument (Montgomery, 2009).

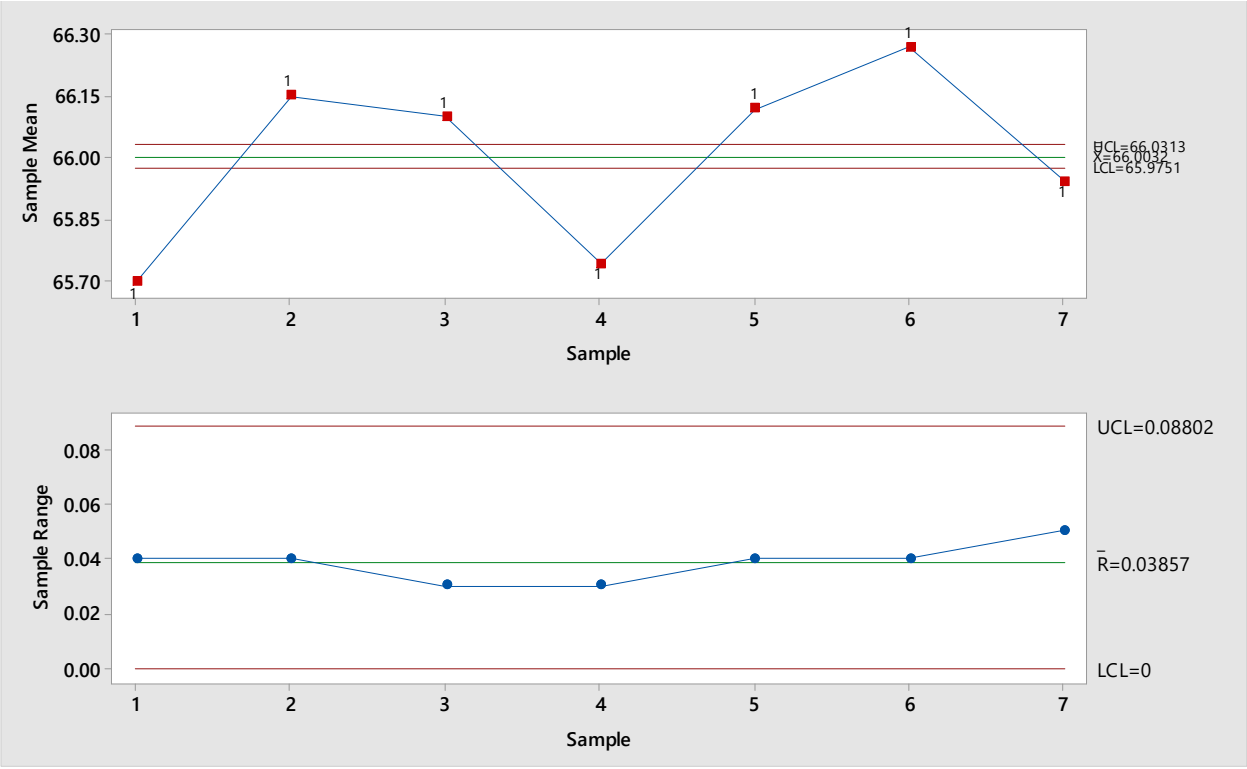


Figure 55: X-Bar and R chart for component 1

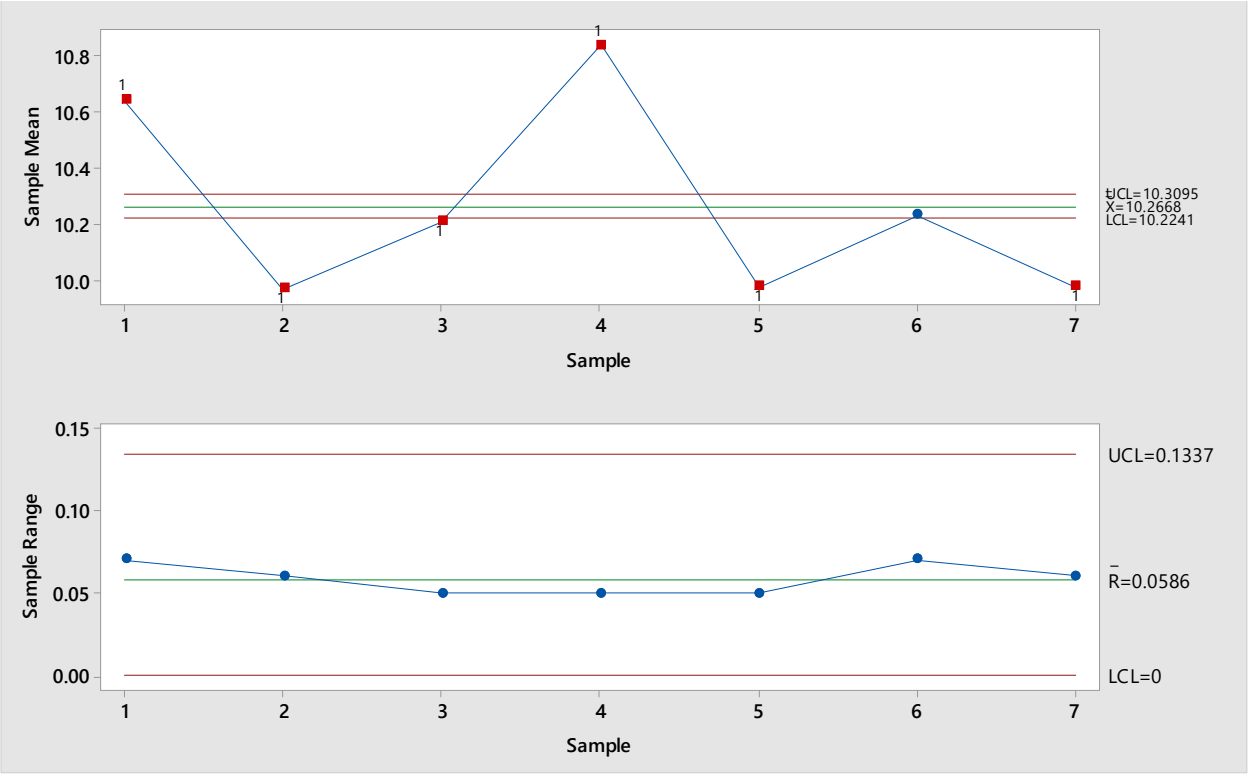


Figure 56: X-bar and R chart for X_1

Repeatability

The capability of an instrument or gauge is well represented by $\sigma_{measuring\ system}$ (See Equation 4)(Montgomery, 2009). The process variation or part-to-part variation can be isolated using Equation 5. The gauge capability is a ratio which can be expressed as a percentage which represents the percentage of variation accounted for by the measuring system. The values returned are approximately 2% and 3% which is well below the 30% maximum acceptance limited discussed in Section 2.2.

Equation 4: Determination of measurement instrument variance

$$\sigma_{measurement\ system} = \frac{\overline{R}}{d_2}$$

Source: (Montgomery, 2009)

Equation 5: Determination of total variation

$$\sigma^2_{process} = \sigma^2_{total} - \sigma^2_{measurement\ system}$$

Source : (Montgomery, 2009)

$$\sigma_{process} = \sqrt{\sigma^2_{total} - \sigma^2_{measurement\ system}}$$

Finally, the estimate of the gauge capability compared to the specification tolerance (USL – LSL) is generally a good measure of adequate measuring capability of the instrument (Montgomery, 2009). The precision-to-tolerance (P/T) ratio highlights the instrument's capability of accuracy within the tolerance bands. A P/T ≤ 0.1

is accepted. Table 24 illustrates the results discussed in the above sections. The P/T ratio for both measured characteristics are below the required 0.1, indicating an acceptable accuracy of the instrument within the specification tolerance.

Table 24: Measurement system capability summary for the near-infrared spectroscopy (NIR)

Instrument	$\bar{R}$	d_2 (4 subgroups)	σ_{Total}	σ_{ms}	$\sigma_{process}$	$P/T\ Ratio$
NIR	0.03857	2.059	0.205409	0.018732	0.204553	0.04
	0.05860	2.059	0.329557	0.028460	0.328326	0.09

The results obtained from the measurement system capability study are satisfactory. The evaluation of sensitivity indicates an instrument with sufficient sensitivity to discriminate between different levels within the tolerance band of the tested sample. The analysis also indicates that the analyst can easily repeat the analysis and return the same results as indicated by the stable R-Bar chart. Finally, the measurement system variation and the precision-to-tolerance ratio indicates an instrument which contributes little to no variation to the overall process variation and is capable of returning accurate measurements when compared to the allowed tolerance of the measured characteristic. The instrument can be accepted as qualified and is fit for analysing the raw material compositions.

5.6.1.2. Gauge repeatability and reproducibility study (GRR)

While the previous section evaluated certain aspects of the MSA in order to 'qualify' the method as per the organisations standards, this section evaluates the 'traditional' GRR using Minitab®. The sample is inspected by two analysts for composition of three different characteristics. Seven samples were analysed in fourfold and tested for three different characteristics. The data was structured as illustrated in Table 25 and then analysed using the GRR function of Minitab® statistical software.

Table 25: Raw material composition as analysed by two analysts

Sample	Appraiser 1			Appraiser 2		
	Component 1	Component 2	X_1	Component 1	Component 2	X_1
1	65.68	23.66	10.67	65.47	23.53	11.00
1	65.70	23.70	10.60	65.49	23.67	10.84
1	65.68	23.66	10.66	65.46	23.58	10.96
1	65.72	23.63	10.65	65.42	23.69	10.89
2	66.15	23.88	9.98	66.17	23.74	10.09
2	66.18	23.58	9.97	66.12	23.79	10.09
2	66.14	23.92	9.94	66.05	23.83	10.12
2	66.14	23.85	10.00	66.12	23.78	10.10
3	66.09	23.70	10.21	66.00	23.78	10.22
3	66.09	23.67	10.23	66.07	23.65	10.28
3	66.10	23.67	10.23	66.02	23.71	10.27
3	66.12	23.70	10.18	66.02	23.71	10.27
4	65.73	23.41	10.86	65.46	23.53	11.01
4	65.76	23.43	10.81	65.49	23.50	11.01
4	65.73	23.41	10.86	65.51	23.42	11.07
4	65.75	23.41	10.84	65.55	23.48	10.97
5	66.13	23.87	10.01	65.66	24.21	10.13
5	66.09	23.94	9.97	65.98	23.83	10.19
5	66.13	23.89	9.98	65.94	23.91	10.15
5	66.13	23.90	9.96	65.74	24.19	10.07
6	66.27	23.46	10.27	66.16	23.49	10.35
6	66.29	23.51	10.20	66.23	23.55	10.22
6	66.25	23.52	10.23	66.23	23.54	10.23
6	66.27	23.49	10.24	66.26	23.50	10.24
7	65.97	24.04	9.99	65.84	24.11	10.05
7	65.92	24.08	10.00	65.71	24.25	10.04
7	65.94	24.12	9.94	65.72	24.26	10.02
7	65.94	24.07	9.99	65.64	24.36	10.00
Min	65.68	23.41	9.94	65.42	23.42	10.00
Max	66.29	24.12	10.86	66.26	24.36	11.07
Mean	66.00	23.72	10.27	65.84	23.77	10.39
Range	0.61	0.71	0.92	0.84	0.94	1.07
STDEV	0.2054	0.2234	0.3296	0.2867	0.2758	0.3848

Figure 57 and Figure 58 illustrate the GRR results using Minitab® statistical software. The total gauge variation contributed to 33.78 % of the overall variation. This is seen as unacceptable as the required variation should be ≤ 30 %.

Reproducibility

Reviewing Figure 57, it is evident that the analysts could easily reproduce similar measurements with 12.06% variation contributed by the analyst-part interaction. The percentage variation contributed by the analysts is acceptable.

Repeatability

Figure 57 and Figure 58 illustrate the GRR results for the raw material analysis. The repeatability of the instrument contributes to 31.55% of the total variation with the GRR indicating a total measurement system variation of 33.78%. Given that this exceeds the 30% guideline for MSA, the samples will be tested in duplicate. A quality control sample (known value) will be analysed with all the samples to identify any bias.

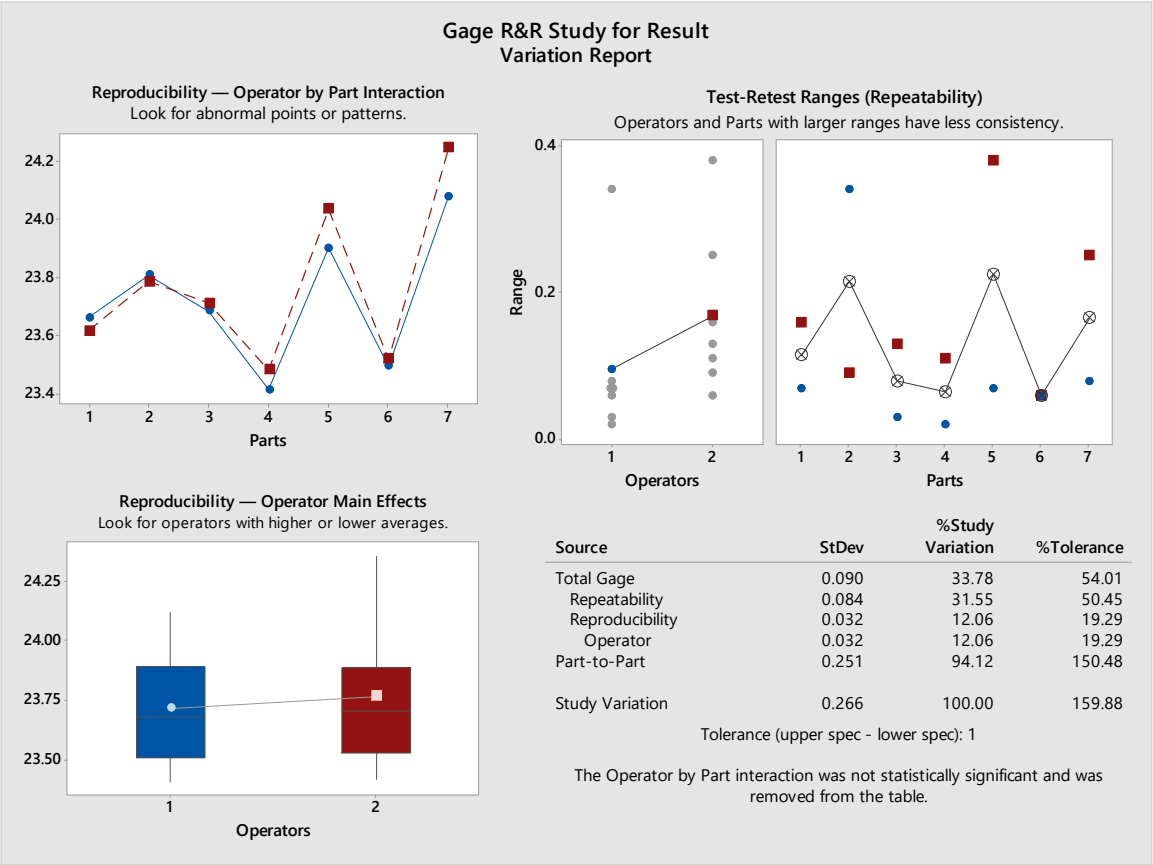


Figure 57: Gauge R&R Study: Variation report for measurement systems analysis using Minitab®

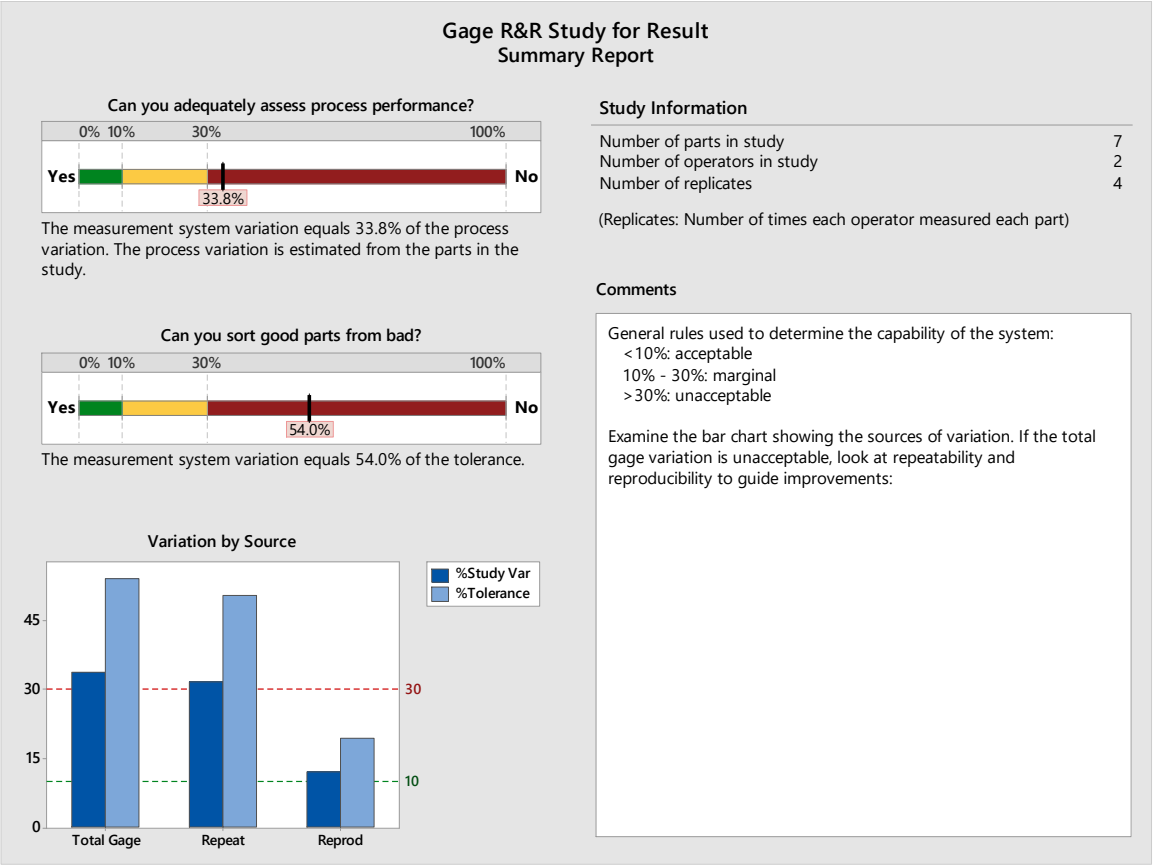


Figure 58: Summary report for measurement systems analysis using Minitab®

5.6.2. Field measuring instruments

Field instrumentation is utilised to measure process parameters, which returns measurements to a control system or operator to control parameters within a specified range. Subsequently, this affects the final product characteristics. It is therefore imperative to ensure that the instruments are adequately precise and accurate at all times to ensure an efficient process.

5.6.2.1. Accuracy and precision

An accurate measuring instrument should return an accurate measurement, meaning returning a value free of bias (AIAG, 2010). To ensure that measuring instruments are free of bias, the instruments are on an annual calibration schedule to ensure linear and stable measurements. The table below illustrates the status of instruments used in the facility for critical readings at the start of the SPC implementation process. The instruments are checked for bias and linearity (drift), and are verified and calibrated at specified intervals. Documented records are calibration certificates for each instrument with an example in Appendix F and the listed equipment for facility α in Table 26. Furthermore, Figure 59 illustrates the calibration process flow constructed to ensure a standardised calibration procedure.

Table 26: Calibration information for instruments used in facility α

Process	Validation/Capability/Verification/Report	Record	Remark
OP10	Calibration Certificate of TIA 1	1	Exp. Date : Sept 2019
OP20	Calibration Certificate of Flow Meter G2	2	Exp. Date : Sept 2019
OP30	Calibration Certificate of TIA-3	3	Exp. Date : Sept 2019
	Calibration Certificate of LICA 4	4	Exp. Date : Sept 2019
OP40	Calibration Certificate of LISCA-5	5	Exp. Date : Sept 2019
OP50	Calibration Certificate of TIRCSA-6	6	Exp. Date : Sept 2019
	Calibration Certificate of TIRCSA-7	7	Exp. Date : Sept 2019
	Calibration Certificate of TIRCSA-8	8	Exp. Date : Sept 2019
	Calibration Certificate of TIRCSA-9	9	Exp. Date : Sept 2019
	Calibration Certificate of TIRCSA-10	10	Exp. Date : Sept 2019
	Calibration certificate for pH meter	N/A	Weekly Verification
OP60	Calibration Certificate of PI 11	11	Exp. Date : Nov 2019
	Calibration Certificate of PI 12	12	Exp. Date : Nov 2019
OP70	Calibration Certificate of TIRCS 13	13	Exp. Date : Sept 2019
	Calibration Certificate of TIRCS 14	14	Exp. Date : Sept 2019
	Calibration Certificate of TIRCS 15	15	Exp. Date : Sept 2019
	Calibration Certificate of TIRCS 16	16	Exp. Date : Sept 2019
	Calibration certificate for pH meter	N/A	Weekly Verification

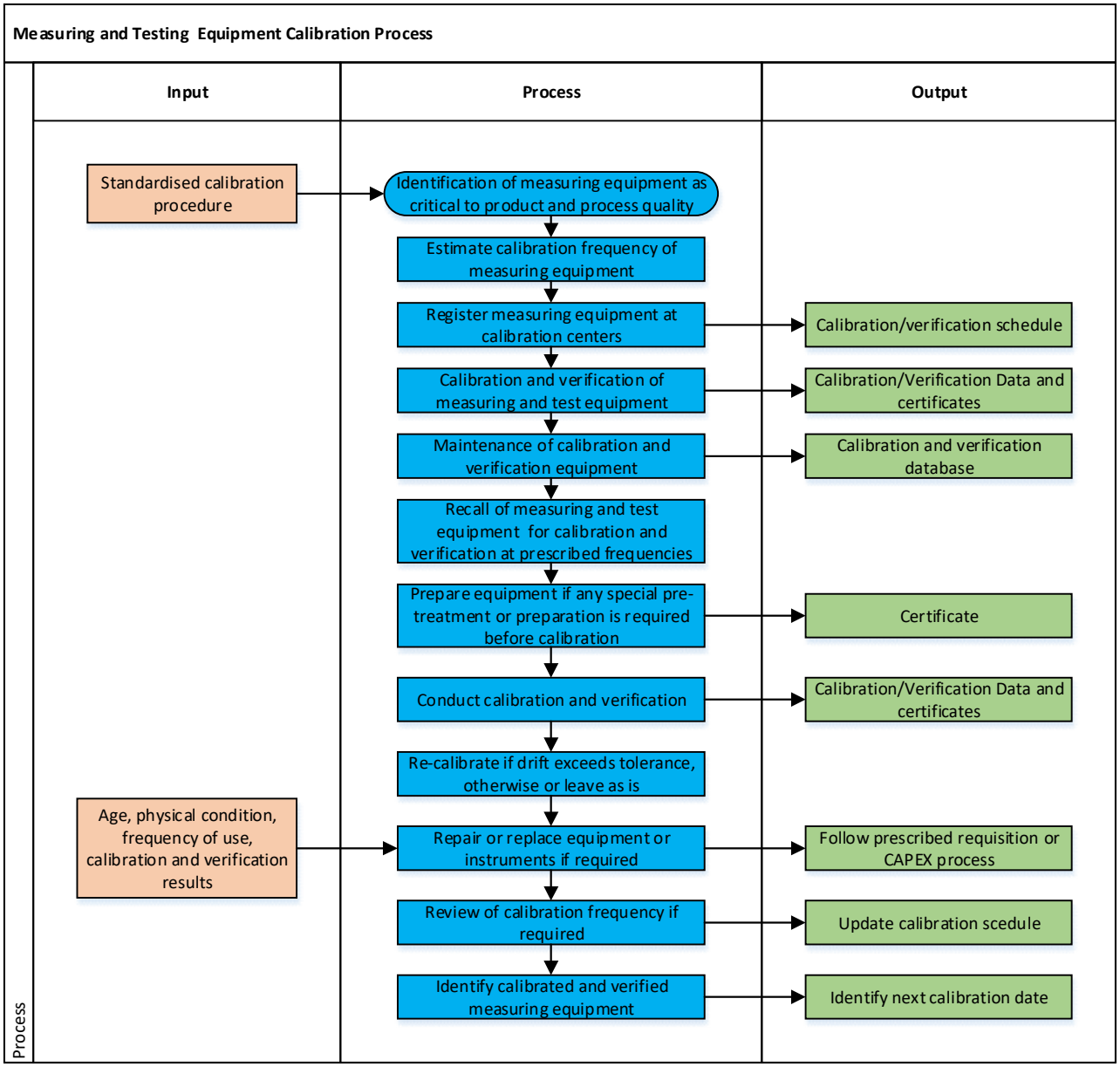


Figure 59: Schematic flow diagram for process calibration

5.6.3. Conclusion

The results obtained from the dataset used for the analytical method qualification and MSA are satisfactory. The annual calibration signifies measuring equipment which is accurate and free from bias. It can be concluded that the measuring system employed for measuring the parameters of the process and the characteristics of the product is both accurate and precise as proven by the above measurement system capability and calibration studies. The measurements are precise and accurate and it can be concluded that measurement system is adequate if operated within the means illustrated in each section, with specific reference to the duplication of the measurement for raw material composition based on the repeatability of the instrument.

5.7. Control chart selection

The control chart used for the implementation of SPC is the Individual-Moving Range (I-MR) chart. The data used for the implementation of SPC is continuous, homogenous and is not divided into subgroups. The criteria for selection are illustrated in Figure 7.

The I-MR chart was selected. A single sample is measured for every prepared batch prior to it being used in the process. Therefore, an individual subgroup is generated for every measurement and variation should be detected between each measurement as it occurs. Every individual measurement has an effect on the CTQ characteristic of the final product. The I-MR chart selection is supported by Montgomery & Runger (2007), by stating that the generation of each batch sampled is very slow with each measurement being as critical as the next. The long lead time in between samples is not conducive for rational subgrouping. Once the control chart is selected, the baseline is established to ensure proven process performance can be illustrated.

5.8. Establish SPC baseline process performance

The following process evaluation serves as the baseline for the process under investigation. Historical data was analysed for all the operations at facility α.The evaluation for facility α was performed for 13 sub-batches (3 tonnes per sub-batch). The evaluation indicates the level of stability of the process, providing insight on process performance and possible areas for improvement.

5.8.1. Performance evaluation

Raw material feeding and preparation

The first set of characteristics evaluated involves the raw materials fed to the process. The control charts below indicate the stability in the compositions and quantities of these materials fed to the process.

Process control chart for raw material component one

Figure 60 illustrates the raw material component content distribution for the first component. The figure shows that the process is within statistical control and is relatively stable.

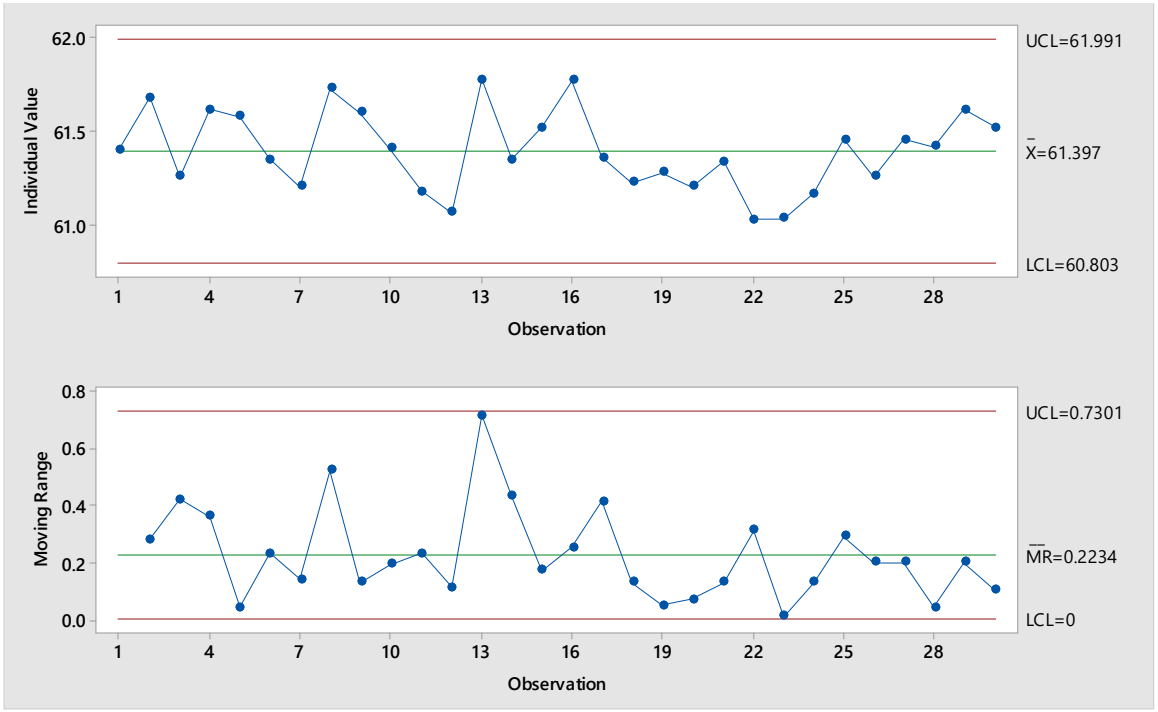


Figure 60: Control chart for raw material component 1

Process control chart for raw material component two

Figure 61 illustrates the raw material component distribution for the second component. The figure confirms that the process is within statistical control and stable.

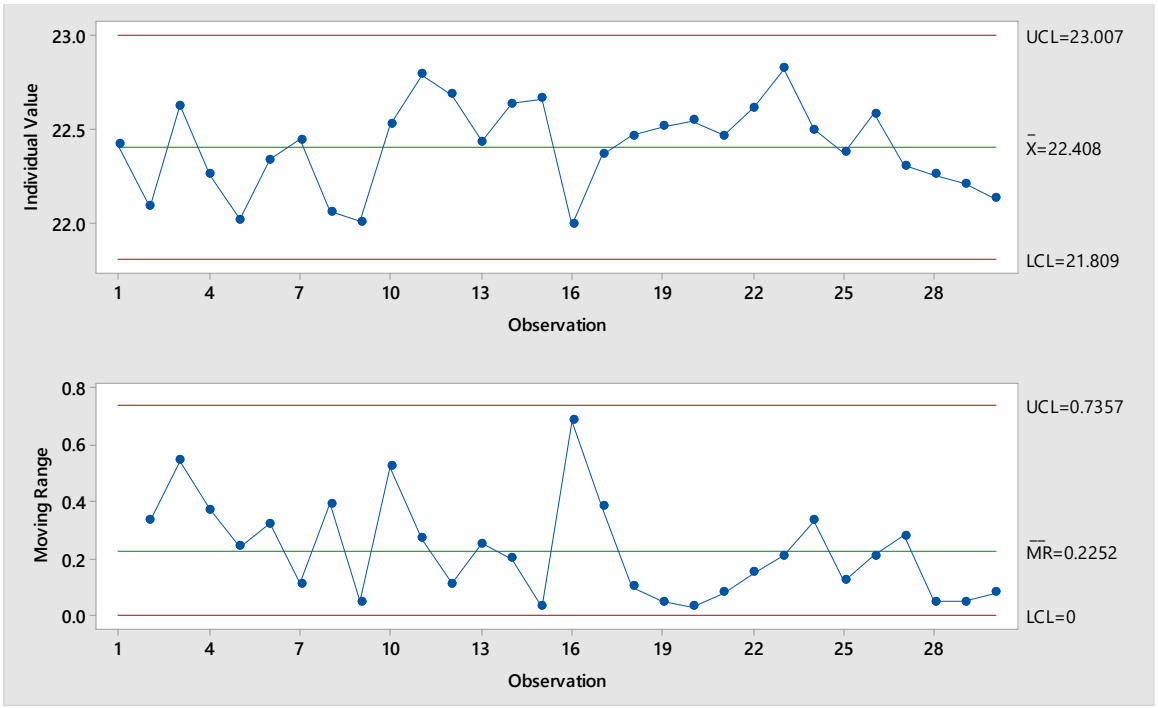


Figure 61: Control chart for raw material component 2

Process control chart for X_1 content

Figure 62 illustrates the X_1 content distribution in the raw material. The figure shows that the process is generally within statistical control. Outliers are present after which the process returns to within control. SPC will be introduced to reduce the randomness of the process.

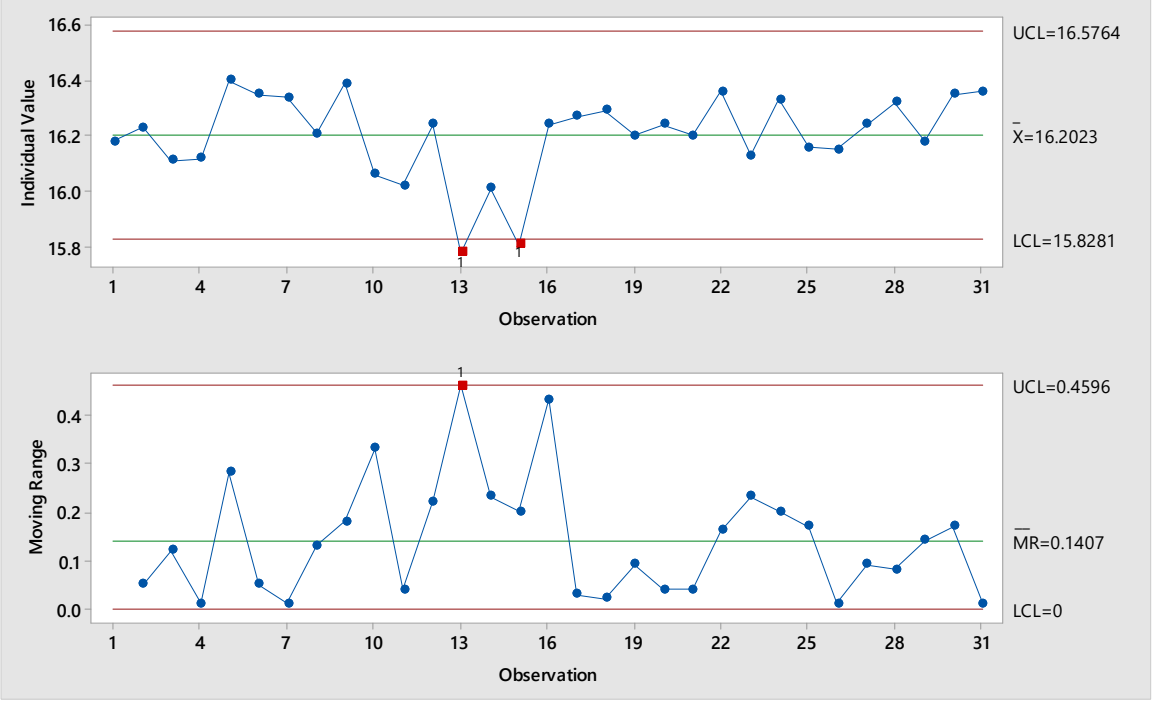


Figure 62: Control chart for X_1

Process control chart for raw material mass

Figure 63 illustrates the raw material mass used per batch of product. The process generally remains within statistical control; however a single outlier is present after which the process returns to within statistical control.

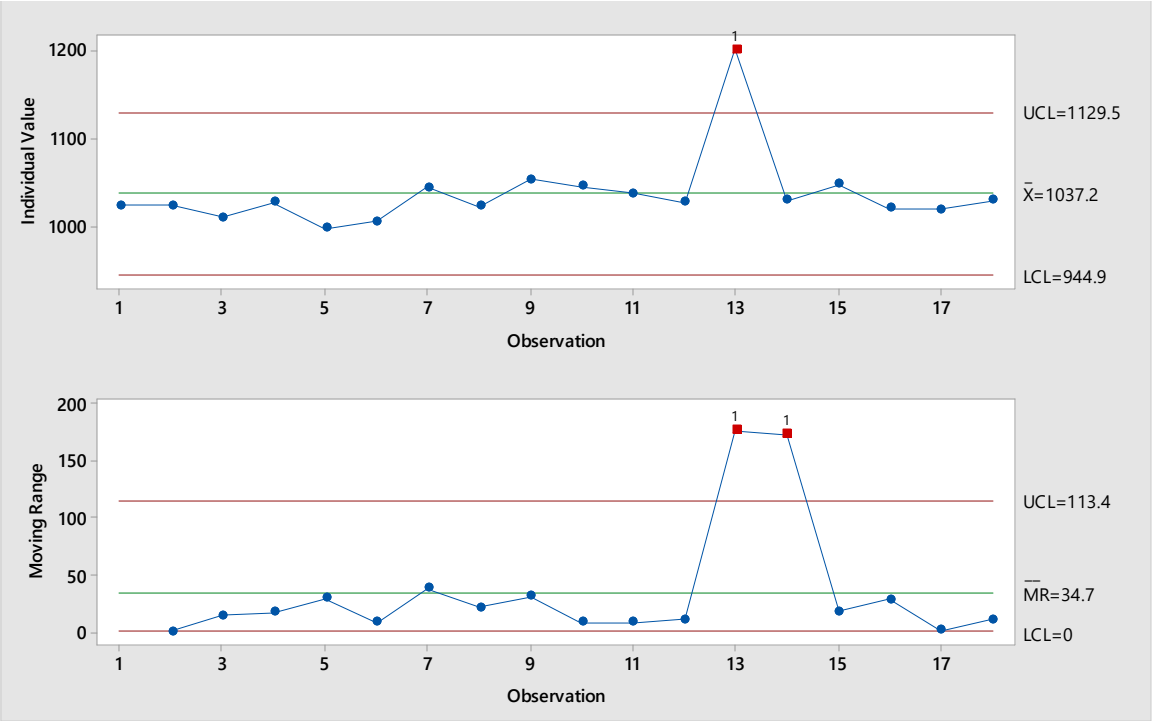


Figure 63: Control chart for raw material mass

Process control chart for raw material temperature

Figure 64 illustrates the daily average raw material temperature distribution. The figure shows that the process is generally within statistical control and stable. The control limits are well within the process specification limits.

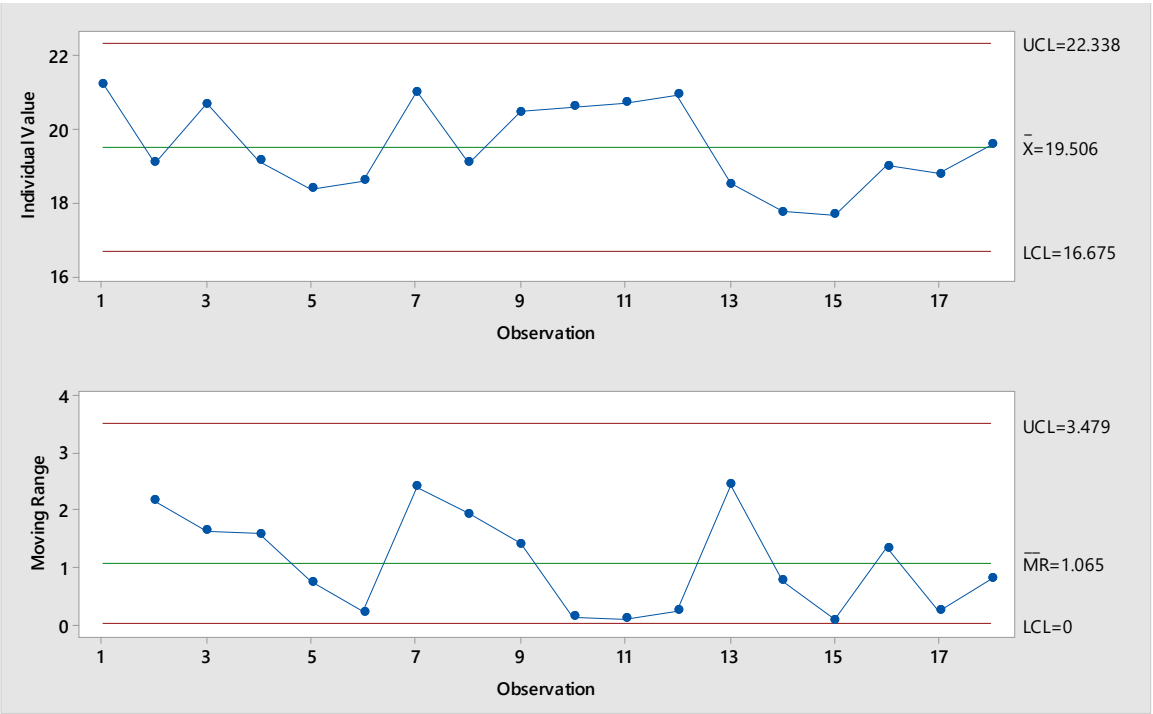


Figure 64: Process control chart for average raw material temperature

The variation in the temperatures of the reactor and reaction can be accounted for during start-up and shut down periods as the vessels are prefilled with the cold buffer tank raw material before the reaction is initiated. Therefore, the initial readings will be low and will periodically increase until the process stabilises to within the specification limits of the process.

Synthesis

The synthesis section of the process entails the premixing of the raw materials prior to the reaction at a controlled temperature and residence time in the reactor. However, the temperature control is not a local function as the feed temperature to the premixing vessels is controlled in order to maintain the temperature for the rest of the downstream process.

Process control chart for mixing temperature

Figure 65 illustrates the daily average mixing temperature distribution. The figure shows that the process is within statistical control with variation around the process mean. The process is stable as indicated by the MR-Chart (Moving Range).

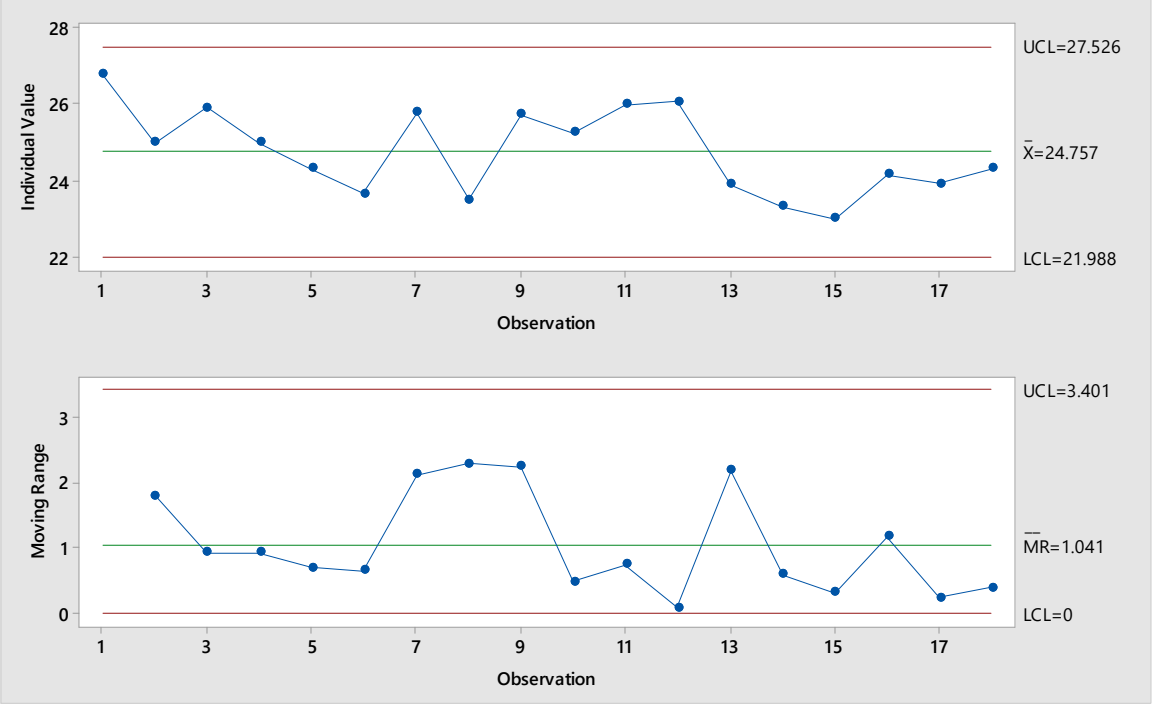


Figure 65: Process control chart for the average mixing temperature

Process control chart for reaction temperature

Figure 66 shows that the process generally remains under statistical control with an outlier on the moving range. The process is generally stable with a single outlier after which it returns to within the MR control limits.

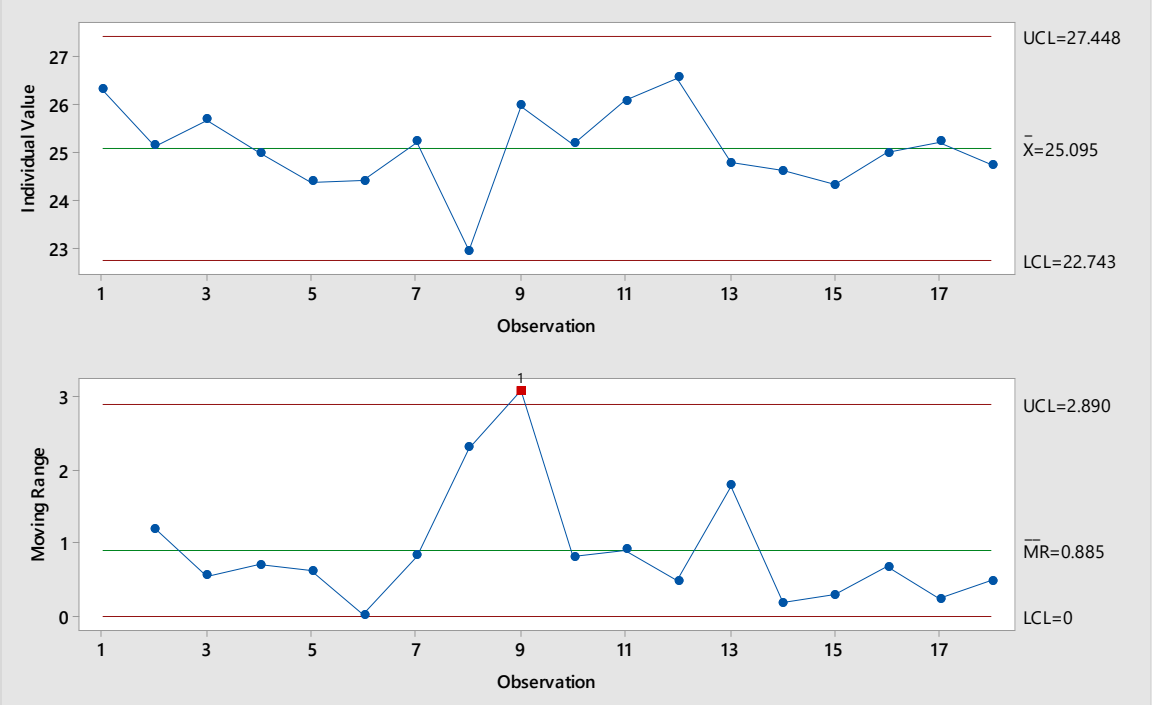


Figure 66: Process control chart for the average reaction temperature distribution

Process control chart for reactor level

Figure 67 illustrates that the above-mentioned process remains within statistical control with natural variation around the process mean. The process is stable.

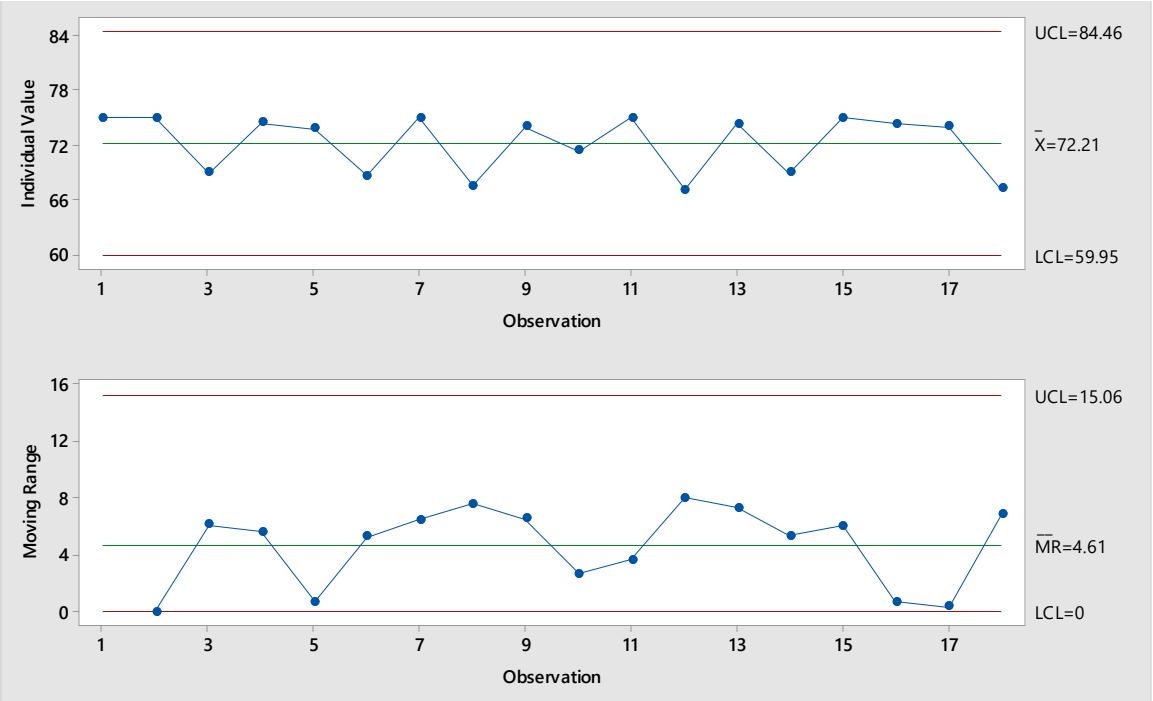


Figure 67: Process control chart for average reactor level

Stabilisation

The stabilisation section is where additional processing and value is added to the product in order to tailor the material to the required specification and also ensure the release of a stable product.

Process control chart for starting pH in pre-stabiliser

Figure 68 shows that the above process remains within statistical control with variation around the process mean. The process is stable.

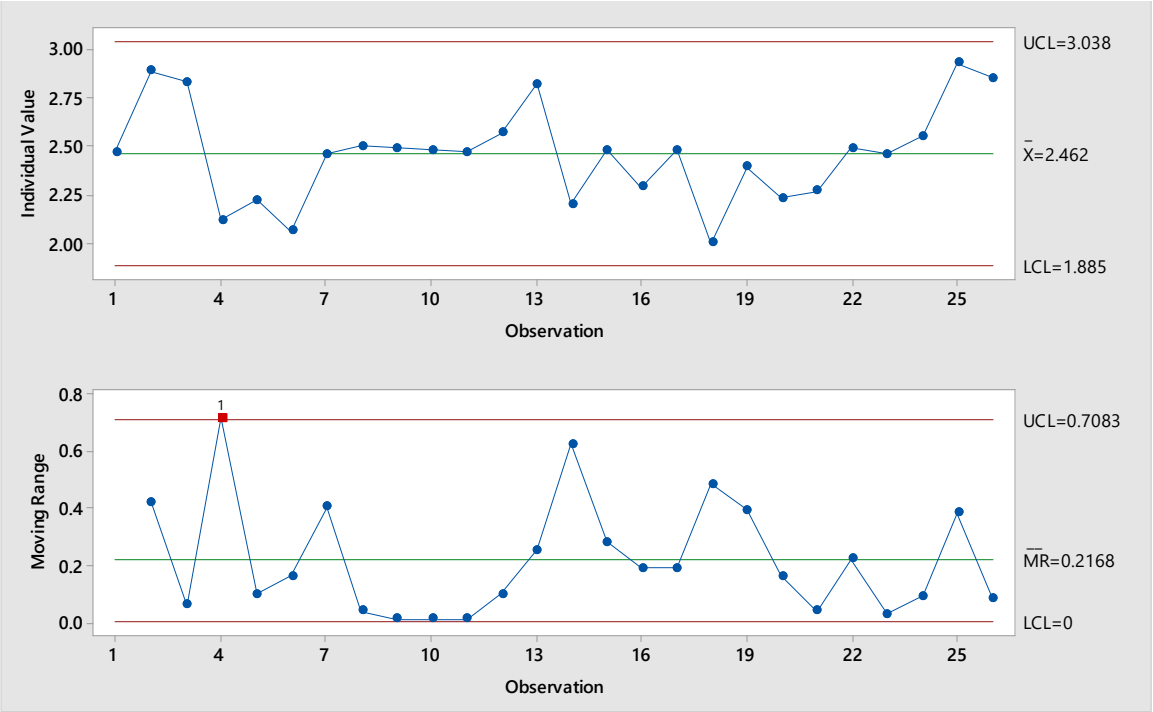


Figure 68: Process control chart for starting pH in pre-stabiliser

Table 27: Material results for evaluated batches

Batch	Y_1	Y_2	Y_3	Y_4	Y_5
1^{1+4}	12.580	180.000	154.000	40.000	0.740
1^{2+6}	12.420	176.000	144.000	40.000	0.910
1^{3+5}	12.530	175.000	143.000	40.000	0.850
2^{1+2}	12.540	179.000	150.000	40.000	0.830
3^{2+3}	12.540	180.000	148.000	40.000	0.680
3^{4+5}	12.470	180.000	140.000	40.000	1.080
3^{1+6}	12.420	163.000	120.000	40.000	0.740
4^{1+3}	12.500	161.000	116.000	40.000	0.900
4^{2+4}	12.500	162.000	114.000	40.000	0.850
4^{5+6}	12.570	179.000	136.000	40.000	1.790
5^{2+3}	12.550	166.000	150.000	40.000	0.960
5^{1+4}	12.510	163.000	104.000	40.000	0.900
5^{5+6}	12.520	165.000	118.000	40.000	0.960

Figure 69 to Figure 73 are control charts for the results illustrated in Table 27. The control charts show that all the processes are within statistical control and thus statistically stable.

Control chart for Y_1 content

Figure 69 shows that the process below starts with two outlying measurements as the process runs out of control. However the process returns to within the two sigma limits and runs below the process means. This is an indication of an out-of-control process. Characteristic Y_1 has been identified as the monitored characteristic for the implementation of SPC.

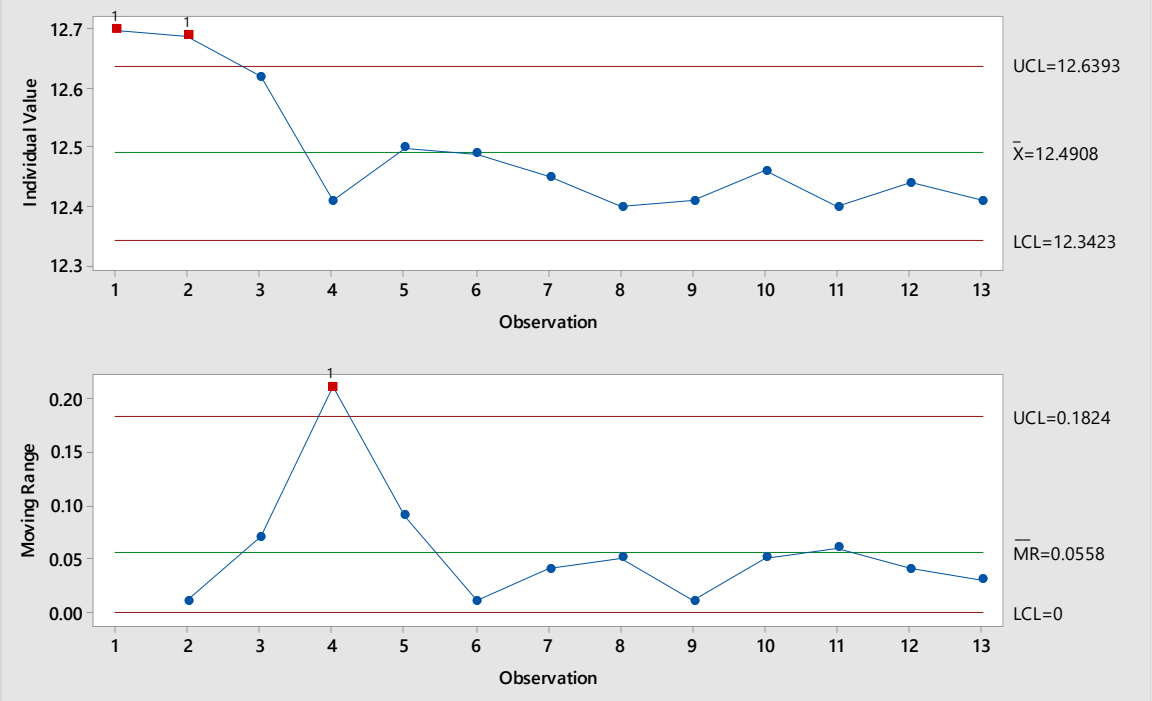


Figure 69: Control chart for Y_1

Control chart for Y_2

Figure 70 shows that the process below is not within statistical control. Major process shifts are present after which the process is stable for a period. The characteristic can be improved with the application of SPC.

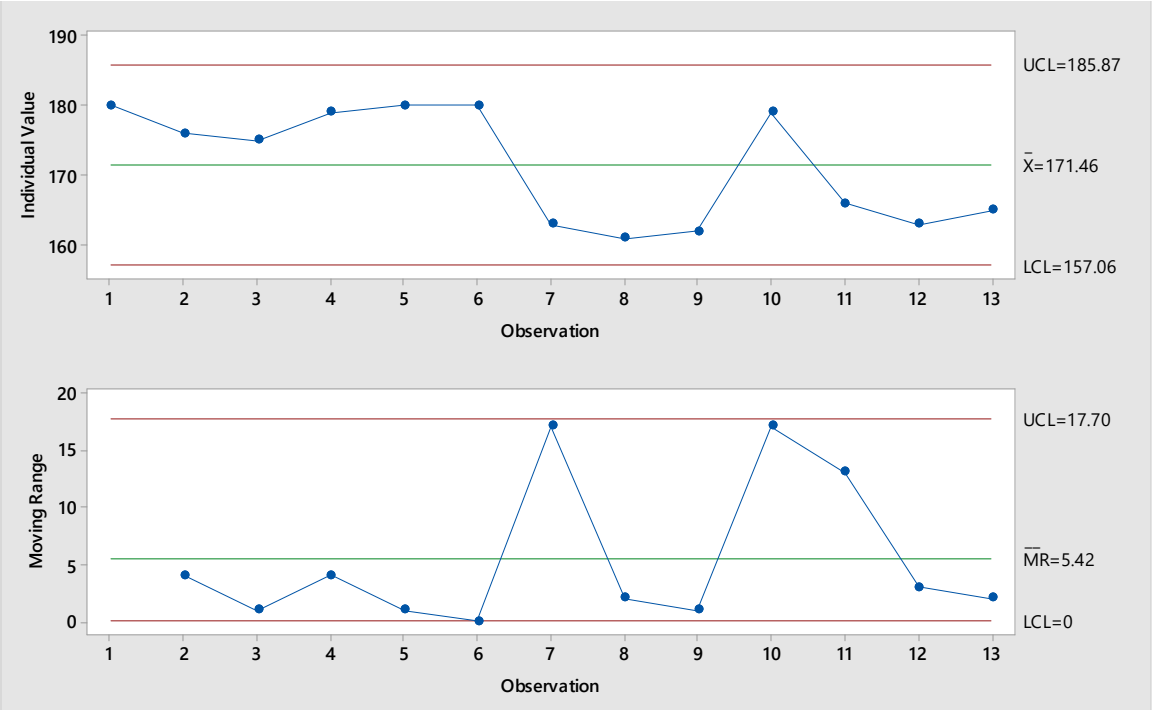


Figure 70: Control chart for Y_2

Control chart for Y_3

Figure 71 shows that the process below is not within statistical control. The process becomes unstable towards the end of the dataset.

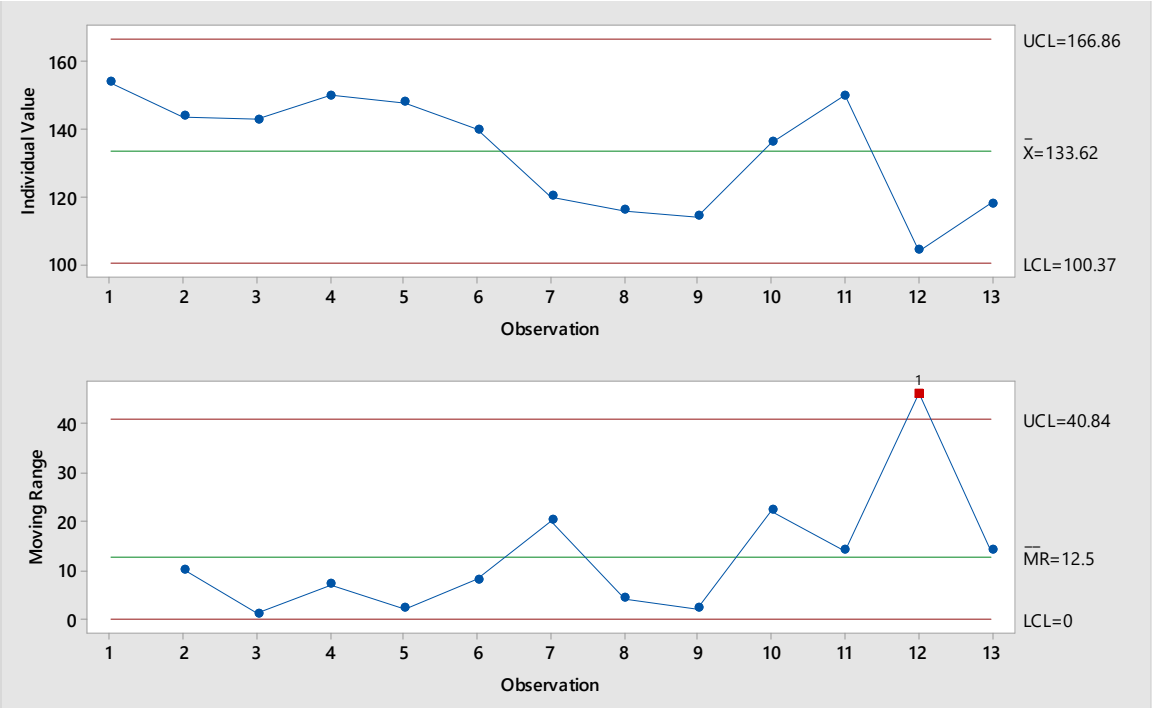


Figure 71: Control chart for Y_3

Control chart for Y_4

Figure 72 illustrates that no variation is present in the below dataset.

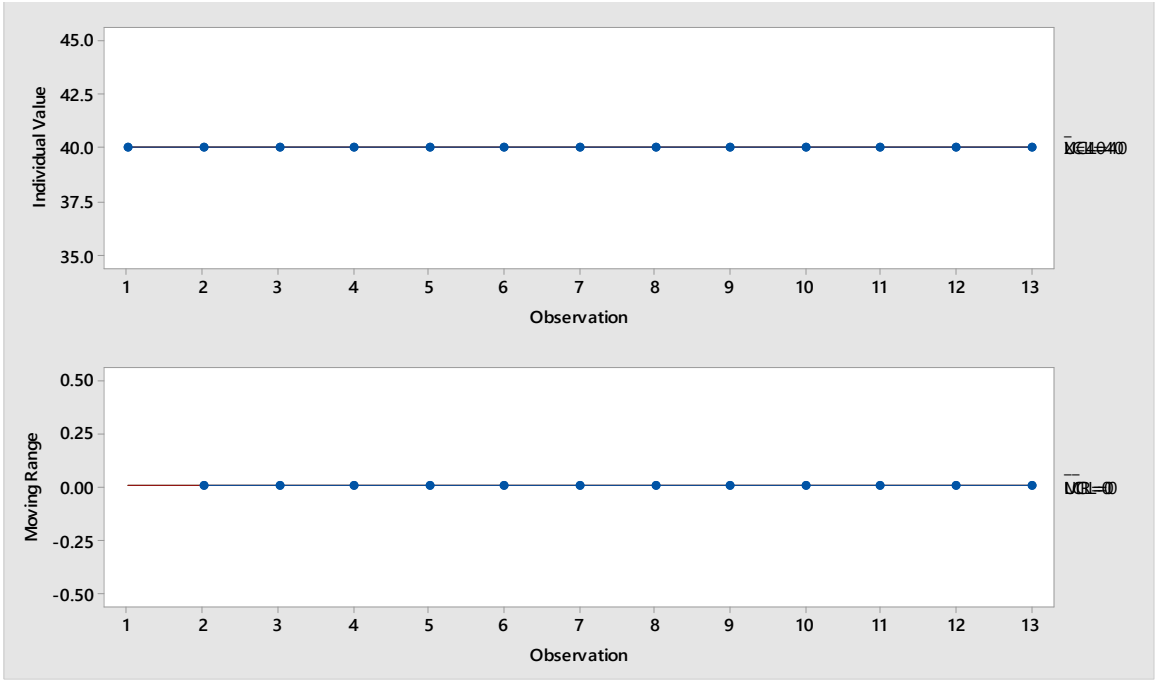


Figure 72: Control chart for Y_4

Control chart for Y_5

Figure 73 shows that the process below generally remains within statistical control with variation around the process mean and two outliers. The process is generally stable with a single outlier after which it returns to within the MR control limits.

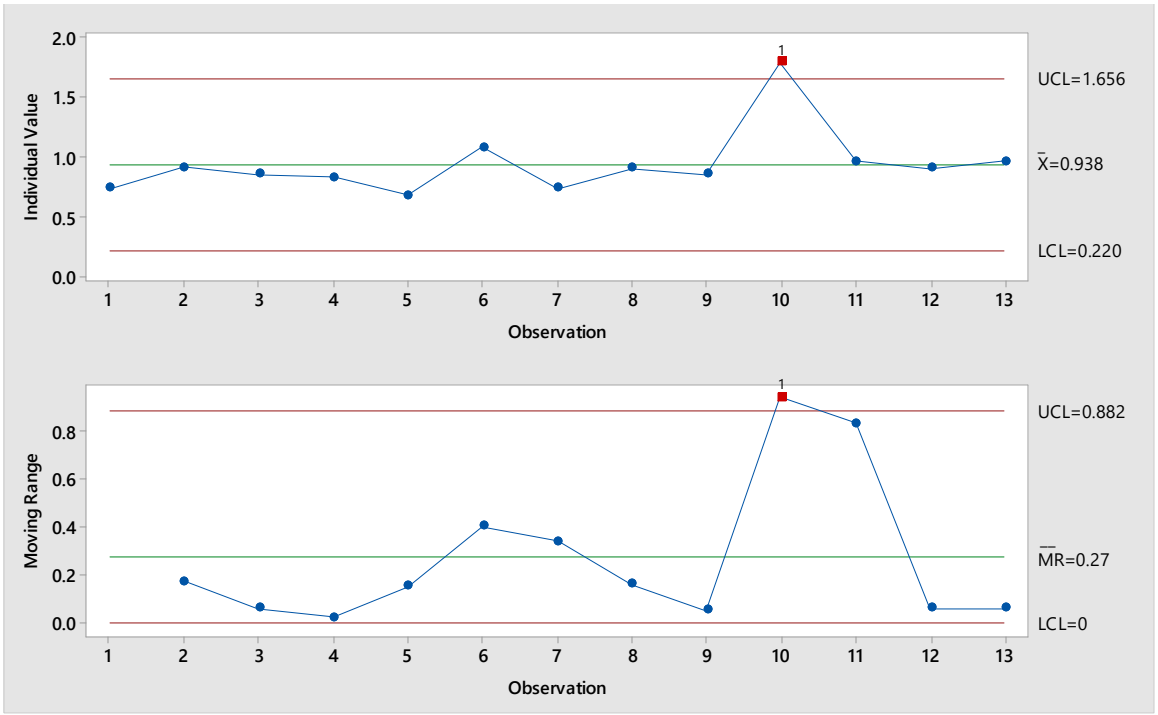


Figure 73: Control chart for Y_5

5.8.2. Conclusion

The control charts and data presented in the report serve as proof that the processes are relatively stable (MR-Charts) and consistent (I-Charts); however, the process is borderline within statistical control and can be improved with the application of SPC. Referring back to Section 5.5, the capability study was performed and the results will form the baseline of the study for the capability analysis. The metrics focused on when monitoring process improvements are displayed in Table 28 and Table 29.

Table 28: Defects recorded per annum for the alpha manufacturing facility

Facility	**Defects recorded on characteristic Y1**
Facility α 2017	42 % (22/55) -
Facility α 2018	78 % (18/23) -

The process has a first time right percentage of 97%, meaning a very low failure rate on final products.

Table 29: Process capability results for identified output characteristics

Characteristics	**C_p**
(Y_1)	0.75
(Y_2)	0.74

The evaluation performed above forms the baseline when measuring the performance after the implementation of SPC. A reduction in the number of defects and a more superior capability index for the same sample size will indicate an improvement in the process.

5.9. SPC cycle and implementation platform

5.9.1. Overview

The implementation platform forms the core operational and functional baseline of the SPC programme as the efficiency of the programme is dependent on the functionality of the platform. Carter (1993) and Rantamäki (2013) both opted for computerised systems in order to automate the recording of data and the generation of control charts. The drawback of a wholly computerised system is that the data fed into the SPC programme should be in a format which the operating system can use, coupled with high costs for an automated computerised system. In most cases manufacturing facilities are old and data is recorded by hand, using check-sheets and field measuring instruments or the data recorder of the SCADA or PLC system which is stand-alone and isolated from any network (Grigg & Walls, 2007). The paper-based system is the most widely used platform where control charts are manually drawn on paper or a whiteboard.

In this specific case study, the platform will consists of various elements. The display and generation of the control charts will be performed using a dashboard reporting system, which sources the information for the construction of the control chart using Microsoft Excel sheets. The information displayed on the control chart for the monitored characteristic will be reported by the laboratory analyst and viewed by the operator. The objective is to use electronic log sheets to record the raw data into Excel. The process will involve the:

1. Design of an electronic excel log sheet.
2. Recording of the check-sheet information into an electronic source.
3. Compilation of background calculations which will be preprogrammed into the electronic sheet.
4. Use of a dashboard reporting system which will display the dynamic control charts on an electronic screen for the operator to monitor in the control room. The compilation of the report will be done by the SPC coordinator.

The platform used for the implementation of SPC proved to be an obstacle. The challenge is to establish a platform equipped for any industry and company.

5.9.2. Control chart platform

Although Minitab® is used for the evaluation of process capability, MSA and control charts, the tool is not dynamic and requires constant manual updates. However, as mentioned in Section 5.7, the samples have a long lead time between measurements. Therefore it is possible to use Minitab®, but with the manual generation of control charts. The accessibility of the charts would be limited in Minitab®. The identified characteristic will be inspected and recorded by an analytical chemist at the laboratory, and the information in relation to previous measurements should be made available to the operator in order to act appropriately.

The following section illustrates the data collection and calculations used for the generation of control charts using Excel and Power BI, to evaluate the functionality of the tool.

5.9.3. Functionality

The functionality of the proposed options for the generation and display of control charts are evaluated. The data was sampled and recorded at the facility. The data is processed using the formulae discussed below and is then presented as displayed in Table 30.

Table 30: Results of calculations used to generate I-MR chart for 30 observations in Excel and Power BI®

Observation	X	X_2	MR	X-Bar	R-Bar	UCLx	LCLx	UCLr	LCLr	Stdev
1	16.18	16.18	0.00	16.20	0.15	16.58	15.81	0.47	0.00	0.1287
2	16.23	16.23	0.05	16.20	0.15	16.58	15.81	0.47	0.00	
3	16.11	16.11	0.12	16.20	0.15	16.58	15.81	0.47	0.00	
4	16.12	16.12	0.01	16.20	0.15	16.58	15.81	0.47	0.00	
5	16.40	16.40	0.28	16.20	0.15	16.58	15.81	0.47	0.00	
6	16.35	16.35	0.05	16.20	0.15	16.58	15.81	0.47	0.00	
7	16.34	16.34	0.01	16.20	0.15	16.58	15.81	0.47	0.00	
8	16.21	16.21	0.13	16.20	0.15	16.58	15.81	0.47	0.00	
9	16.39	16.39	0.18	16.20	0.15	16.58	15.81	0.47	0.00	
10	16.06	16.06	0.33	16.20	0.15	16.58	15.81	0.47	0.00	
11	16.02	16.02	0.04	16.20	0.15	16.58	15.81	0.47	0.00	
12	16.24	16.24	0.22	16.20	0.15	16.58	15.81	0.47	0.00	
13	15.78	15.78	0.46	16.20	0.15	16.58	15.81	0.47	0.00	
14	16.01	16.01	0.23	16.20	0.15	16.58	15.81	0.47	0.00	
15	15.81	15.81	0.20	16.20	0.15	16.58	15.81	0.47	0.00	
16	16.24	16.24	0.43	16.20	0.15	16.58	15.81	0.47	0.00	
17	16.27	16.27	0.03	16.20	0.15	16.58	15.81	0.47	0.00	
18	16.29	16.29	0.02	16.20	0.15	16.58	15.81	0.47	0.00	
19	16.20	16.20	0.09	16.20	0.15	16.58	15.81	0.47	0.00	
20	16.24	16.24	0.04	16.20	0.15	16.58	15.81	0.47	0.00	
21	16.20	16.20	0.04	16.20	0.15	16.58	15.81	0.47	0.00	
22	16.36	16.36	0.16	16.20	0.15	16.58	15.81	0.47	0.00	
23	16.13	16.13	0.23	16.20	0.15	16.58	15.81	0.47	0.00	
24	16.33	16.33	0.20	16.20	0.15	16.58	15.81	0.47	0.00	
25	16.16	16.16	0.17	16.20	0.15	16.58	15.81	0.47	0.00	
26	16.15	16.15	0.01	16.20	0.15	16.58	15.81	0.47	0.00	
27	16.24	16.24	0.09	16.20	0.15	16.58	15.81	0.47	0.00	
28	16.32	16.32	0.08	16.20	0.15	16.58	15.81	0.47	0.00	
29	16.18	16.18	0.14	16.20	0.15	16.58	15.81	0.47	0.00	
30	16.35	16.35	0.17	16.20	0.15	16.58	15.81	0.47	0.00	

The formulae used for the calculation of the limits for the I-MR chart are sourced from Montgomery and Runger (2007) and are:

Equation 6: Formula used to calculate standard deviation.

$$\hat{\sigma} = \frac{\overline{MR}}{d_2}$$

Equation 7: Formula used to calculate the upper control limit of the control chart.

$$UCL = \bar{X} + 3\frac{\overline{MR}}{d_2}$$

Equation 8: Formula used to calculate the lower control limit of the control chart.

$$LCL = \bar{X} - 3\frac{\overline{MR}}{d_2}$$

Equation 9: Formula used to calculate the lower limit of the moving range chart.

$$UCL_R = D_4 * \overline{MR}$$

Equation 10: Formula used to calculate the lower limit of the control chart.

$$LCL_R = D_3 * \overline{MR}$$

With

- $CL_R = \overline{MR}$
- $CL = \bar{x}$
- $\bar{X} = Sample\ Mean$
- $MR_i = |X_i - X_{I-1}|$

The constants used in the formulae are $d_2 = 1.128$ and $D_4 = 3.27$.

5.9.3.1. Excel reporting

The figures below were generated in Excel. The I-MR chart was generated with relative ease and can be updated with relative simplicity. The chart is also preprogrammed with the criteria for the out-of-control points aiding in the identification of out-of-control points.

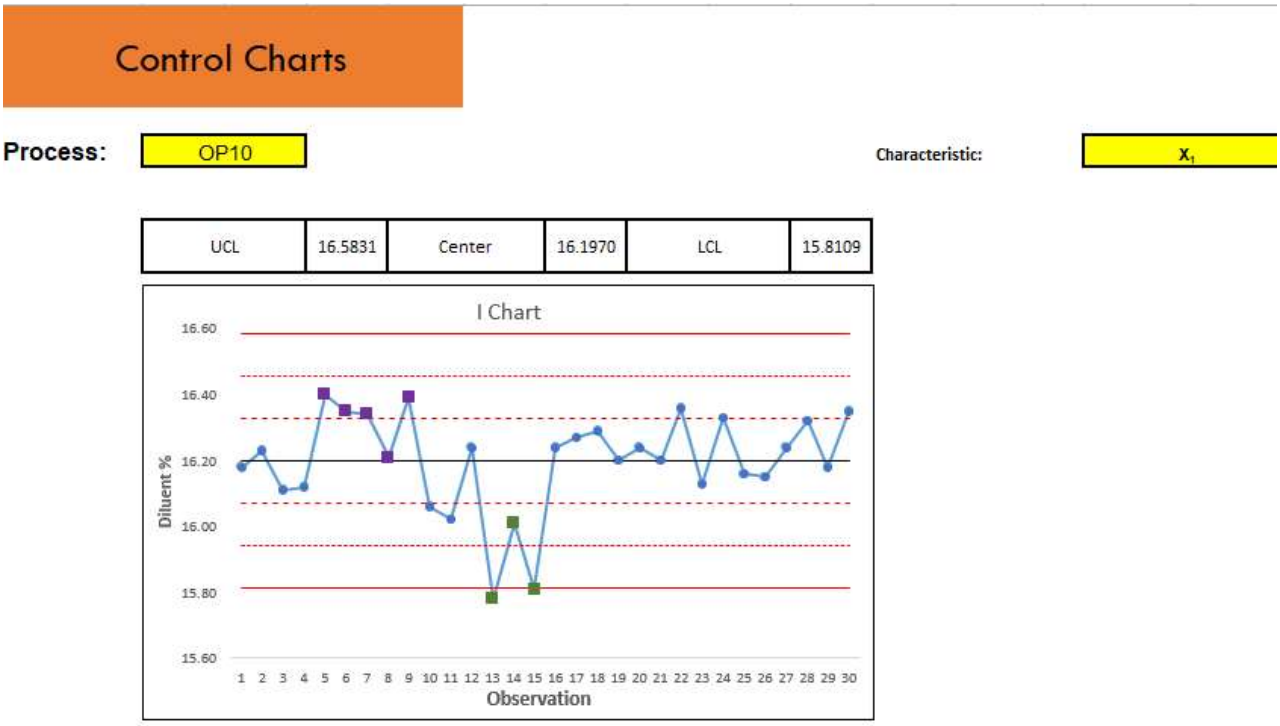


Figure 74: Control chart using Excel as recording and reporting platform

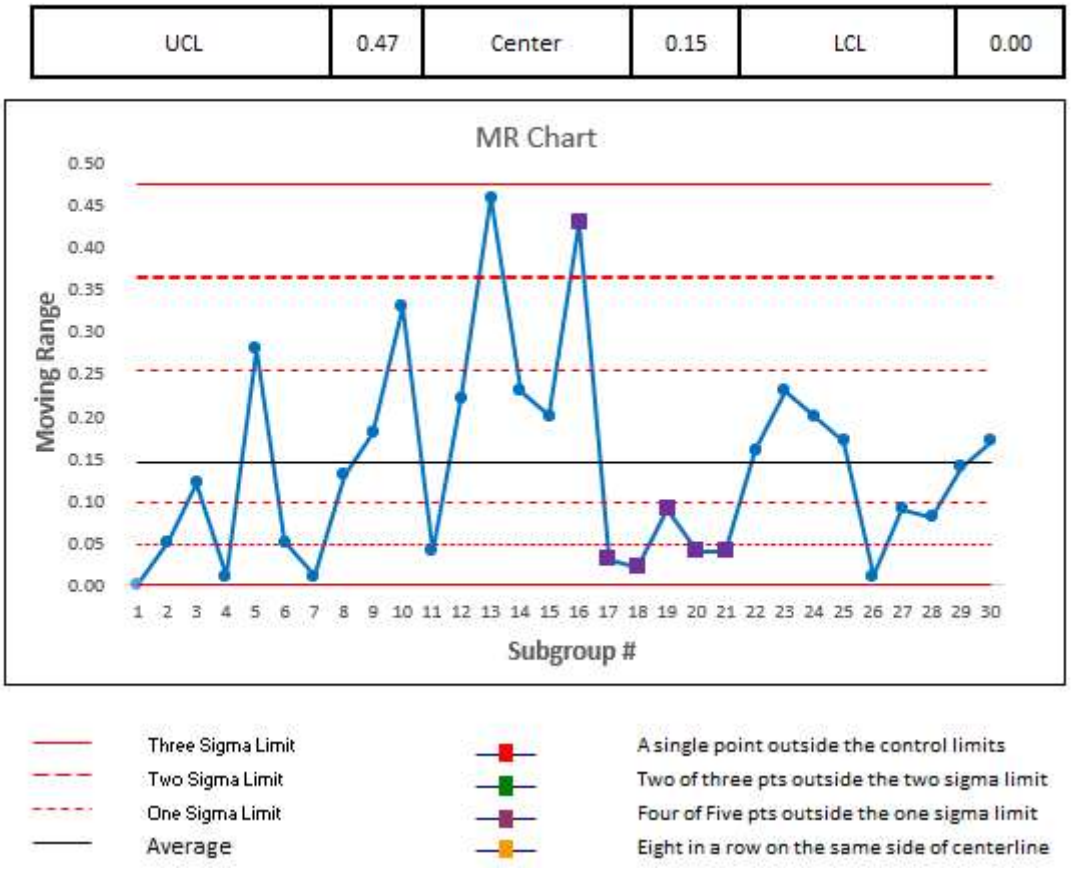


Figure 75: Range chart using Excel as recording and reporting platform

5.9.3.2. Dashboard reporting

The figures below are generated using the Power BI® dashboard reporting system. The data is sourced from the same Excel sheet used for the Excel charts, with the possibility of both charts being operational simultaneously. The construction of the control chart in Power BI requires some exposure to the software, but no prior training was received by the coordinator of the SPC programme. Therefore, the tool is simple enough to be self-taught. The version used was a free version, meaning the programme is accessible. While the software can be preprogrammed to identify out-of-control points, advanced training is required to establish this capability. The dashboard reporting system is preferred, based on the fact that the reports are accessible from any computer with access to the published report and the company-wide intranet. This makes it the preferred option as all the team members can view the report without having to be in the control room of the facility. The reports were all constructed by the SPC coordinator/Quality Engineer who then published the reports onto the dashboard reporting system for all the team members to see.

The dashboard reporting system was used for the implementation of SPC and the charts were published onto the organisation intranet site at:
http://svrswbi/Reports_PBIRS/powerbi/Plant%20Report

Figure 76: I-MR chart using dashboard reporting

With the platform established, the following section will illustrate how the measuring and monitoring is integrated with the out-of-control action plan.

5.10. Monitoring and control OCAP – Out-of-control action plan

The OCAP was alluded to in some of the published literature, however little to no detail is provided to the reader on how to proceed when an out-of-control point occurs. The bulk of the implementation frameworks lacked any problem-solving methodology, therefore this section will attempt to close this gap by providing a structured approach to dealing with out-of-control points. The methods proposed are standard procedures utilised in the case study environment when addressing problems.

The problem-solving approach consists of the FMEA and the 8D problem-solving methodology. The 8D will serve as an approach to tackle problems with no existing solutions. The FMEA will be a working and live document frequently updated as new problems and solutions surface. The FMEA serves as an approach to address potential or reoccurring issues. One of the essential differences between the two methods is that the 8D action is taken to remedy faults and eliminate their causes after the non-compliance occurs (Kumar & Adaveesh, 2017), while the FMEA tries to anticipate possible issues (Alexa & Kiss, 2018). The template for the 8D methodology can be found in Appendix E with an example of the FMEA utilised illustrated in Appendix D, Table 36.

5.10.1. Proposed sequence of events when dealing with assignable cause variation/out-of-control points

The following sequence of events was followed when monitoring processes for assignable cause variation. In the event that assignable cause variation is detected, the following steps were employed to return the process to its natural operating state.

5.10.1.1. Step 1 – Monitor process for assignable cause variation

Applying the out-of-control criteria discussed in Section 2.7.3.4 . The below steps are the guidelines to be followed when reviewing control charts. It is essential not to make process changes to processes which are only experiencing common cause variation as this may have a negative effect on the process and the process outputs. Follow the steps below when interpreting control charts to prevent unnecessary process adjustments from being made (refer back to Figure 29).

1. One or more points outside of the control limits.
2. Two or three consecutive points outside the two-sigma warning limits but still inside the control limits.
3. Four or five consecutive points beyond the one-sigma limits.
4. A run of eight consecutive points on one side of the centre line.
5. Six points in a row steadily increasing or decreasing.
6. Fifteen points in a row in zone C (both above and below the centre line).
7. Fourteen points in a row alternating up and down.
8. Eight points in a row on both sides of the centre line with none in zone C.

9. An unusual or non-random pattern in the data.
10. One or more points near a warning or control limit

Figure 77 portrays the results for X_1 plotted on a control chart. When applying the above-mentioned points it is clear that between observations 6 and 13 the process is running out of control, as explained by rule number 2. This triggers the out-of-control action plan as indicated in Figure 78. Minitab® was used to generate the control charts for reporting purposes.

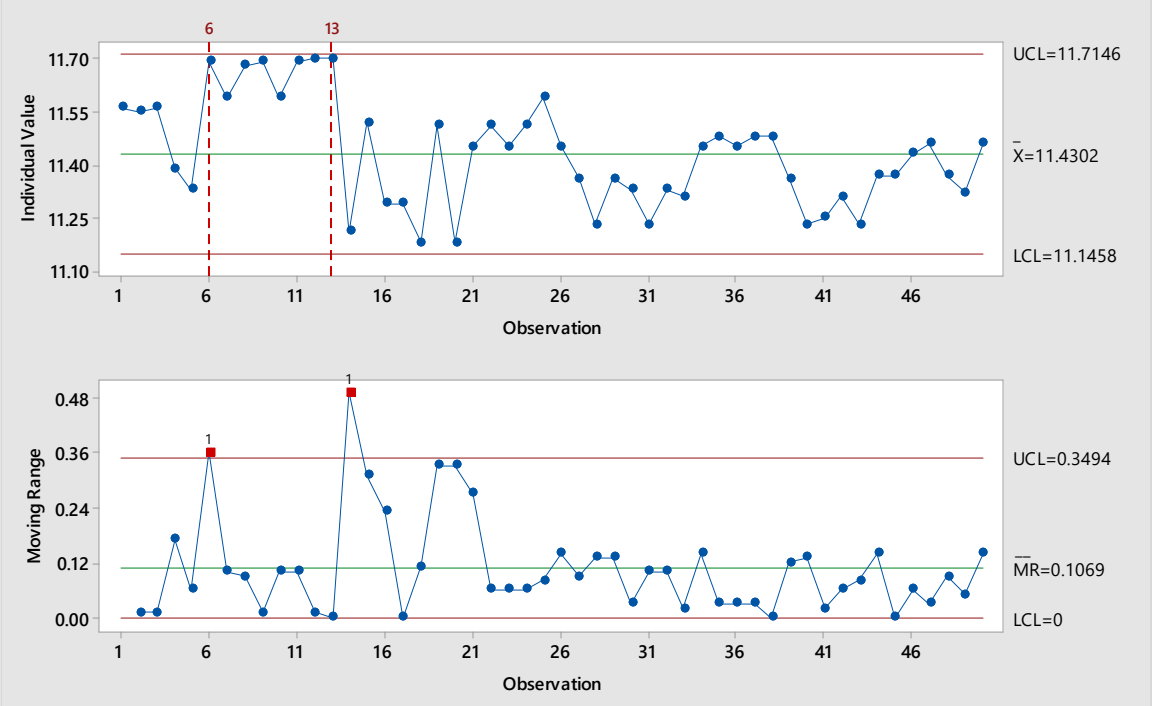


Figure 77: Control chart for X_1

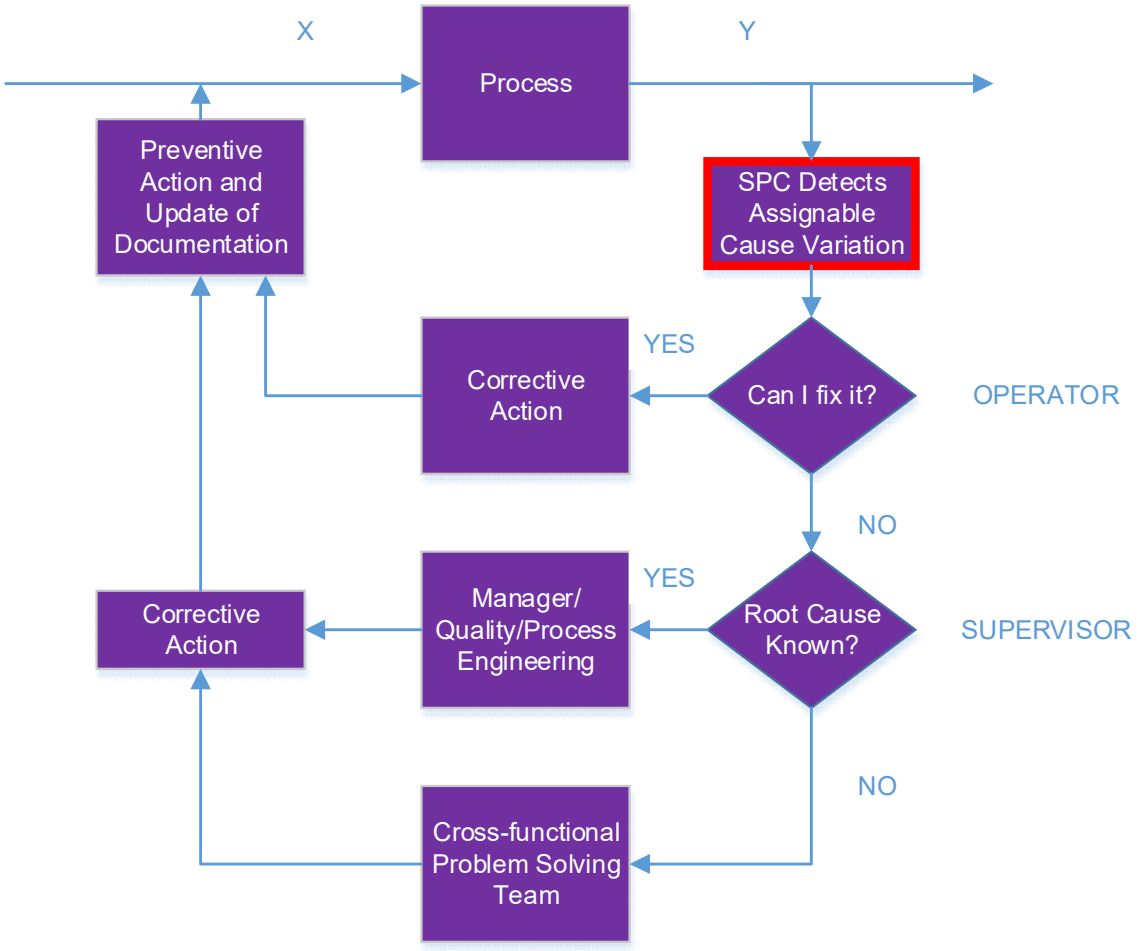


Figure 78: Graphical illustration of the out-of-control action plan where assignable cause is detected.

5.10.1.2. Step 2 – Immediate action using the FMEA

Upon indication of the assignable cause variation, the initial reaction to the situation will be the use of the FMEA by the process operator. As discussed in Section 2.8 and Section 4.3.12, the FMEA is a tool which anticipates failure with possible corrective actions for the specific failure. The core structure of the FMEA is presented and illustrated as a failure mode in Table 36 in Appendix E. Therefore, the purpose of the FMEA is to be a live document on which all possible failure modes of the process can be documented. The operator will consult the FMEA in the case of a 'process failure' and can implement the appropriate corrective action. The FMEA document will be controlled by process engineering with inputs from the manufacturing department. The operator identifies the possible root cause of the failure mode and implements the appropriate corrective action. Upon implementation, the process is monitored for effectiveness of the corrective action which becomes a permanent action if the process returns to its natural operating state. The process is documented and all relative manufacturing documentation can be updated.

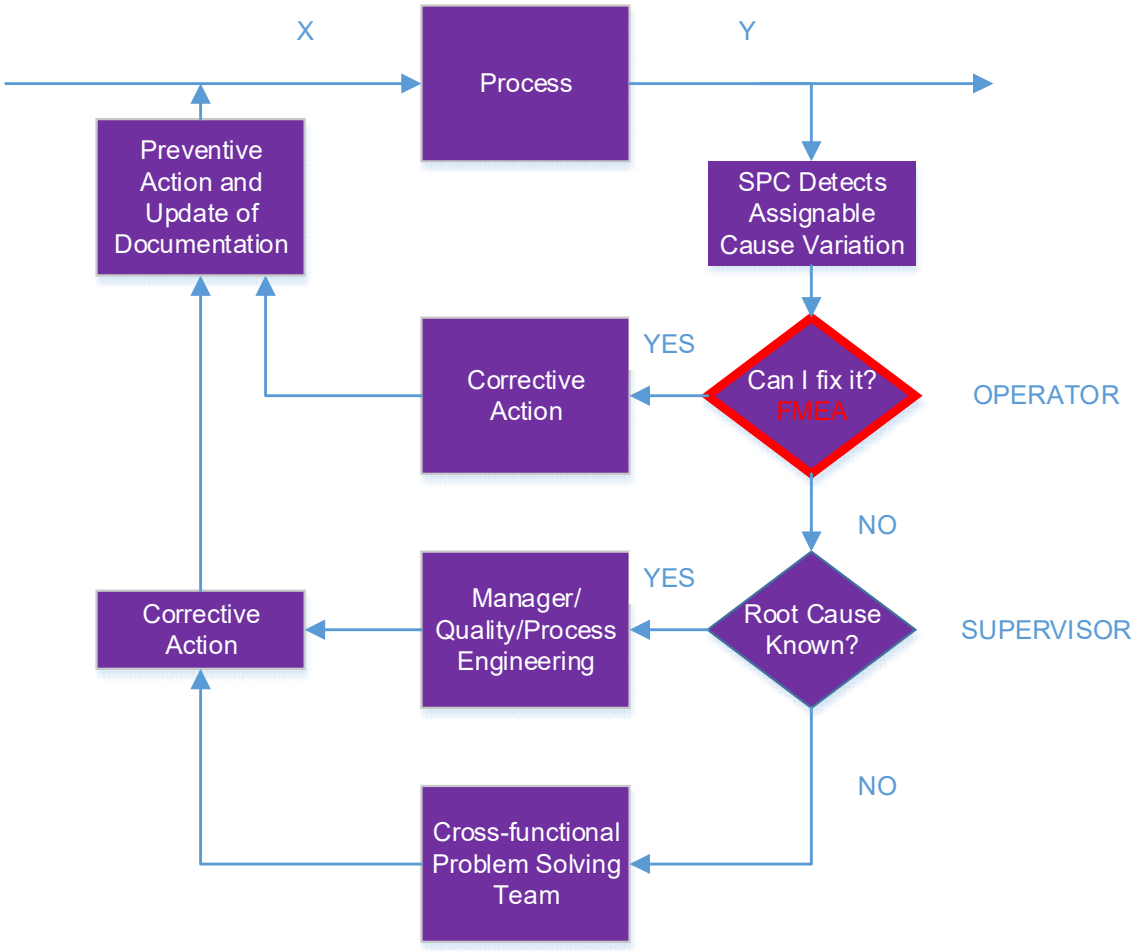


Figure 79: Graphical illustration of the out-of-control action plan for rapid problem-solving.

The operator reviewed the operation and the possible failure modes. Upon evaluating all the possibilities, the operator noticed the increase in reaction temperature; coupled with a drop in discharge pressure. This immediately triggered the operator to alert his superior and requested him to summon the maintenance department to assess the damage to the mechanical seal of the pump. A change in pressure at the mechanical seal of the pump indicates water ingress into the product line from the seal side, which then reacts with the material in the pipe causing a neutralisation reaction, which generates heat in the reaction. The water ingress decreases the concentration of component X_1 in the composition of the feed to the reactor. Non-conforming raw material composition (X_1 concentration) will lead to a non-conforming batch of product (Y_1 characteristic), if not corrected in time. The operator contacted his colleague in the receiving building and informed him that he will be stopping the process for the pump to be inspected, before they commence with the next batch. As stated by Ali (1992), the application of the FMEA fosters quality material by identifying the problem in process, before it severely affects the final product. Therefore, the FMEA was used to diagnose the cause of a failure mode preventing the potential negative consequence on Y_1 by controlling X_1.

Table 31: FMEA Template used for OCAP problem solving

No	Component / function	Potential Failure Mode(s)	Potential effect of the failure	Classification	Causes	Corrective action	Sev	Occ	Det	RPN
OP10	Raw Material Mixing	Raw material (X_1) composition out of specification	Y_1 out of specification	MA	Operator error	Sample and adjust raw material accordingly	8	1	1	8
				MA	Stirring inadequate	Maintenance, stirring time	8	1	3	24
				MA	Control system wear/failure	Maintenance, instrument failure detected on the SCADA	8	1	3	24
				MA	Water ingress (Mechanical seal failure)	Temperature increase during reaction – operator action required	8	2	8	128

The operator reviewed the operation and the possible failure modes. Upon evaluating all the possibilities, the operator noticed the increase in reaction temperature; coupled with a drop in discharge pressure. This immediately triggered the operator to alert his superior and requested him to summon the maintenance department to assess the damage to the mechanical seal of the pump. A change in pressure at the mechanical seal of the pump indicates water ingress into the product line from the seal side, which then reacts with the material in the pipe causing a neutralisation reaction, which generates heat in the reaction. The water ingress decreases the concentration of component X_1 in the composition of the feed to the reactor. Non-conforming raw material composition (X_1 concentration) will lead to a non-conforming batch of product (Y_1 characteristic), if not corrected in time. The operator contacted his colleague in the receiving building and informed him that he will be stopping the process for the pump to be inspected, before they commence with the next batch. As stated by Ali (1992), the application of the FMEA fosters quality material by identifying the problem in process, before it severely affects the final product. Therefore, the FMEA was used to diagnose the cause of a failure mode preventing the potential negative consequence on Y_1 by controlling X_1. Subsequently it was never necessary to employ the 8D problem-solving methodology, although the next section elaborates on a problem that has been solved using the 8D to illustrate the problem-solving and organisational learning power of the tool.

5.10.1.3. Investigation into assignable cause variation using a cross-functional team

The steps of the 8D problem-solving methodology are discussed in Section 2.9 and a completed template can be found in Appendix F.

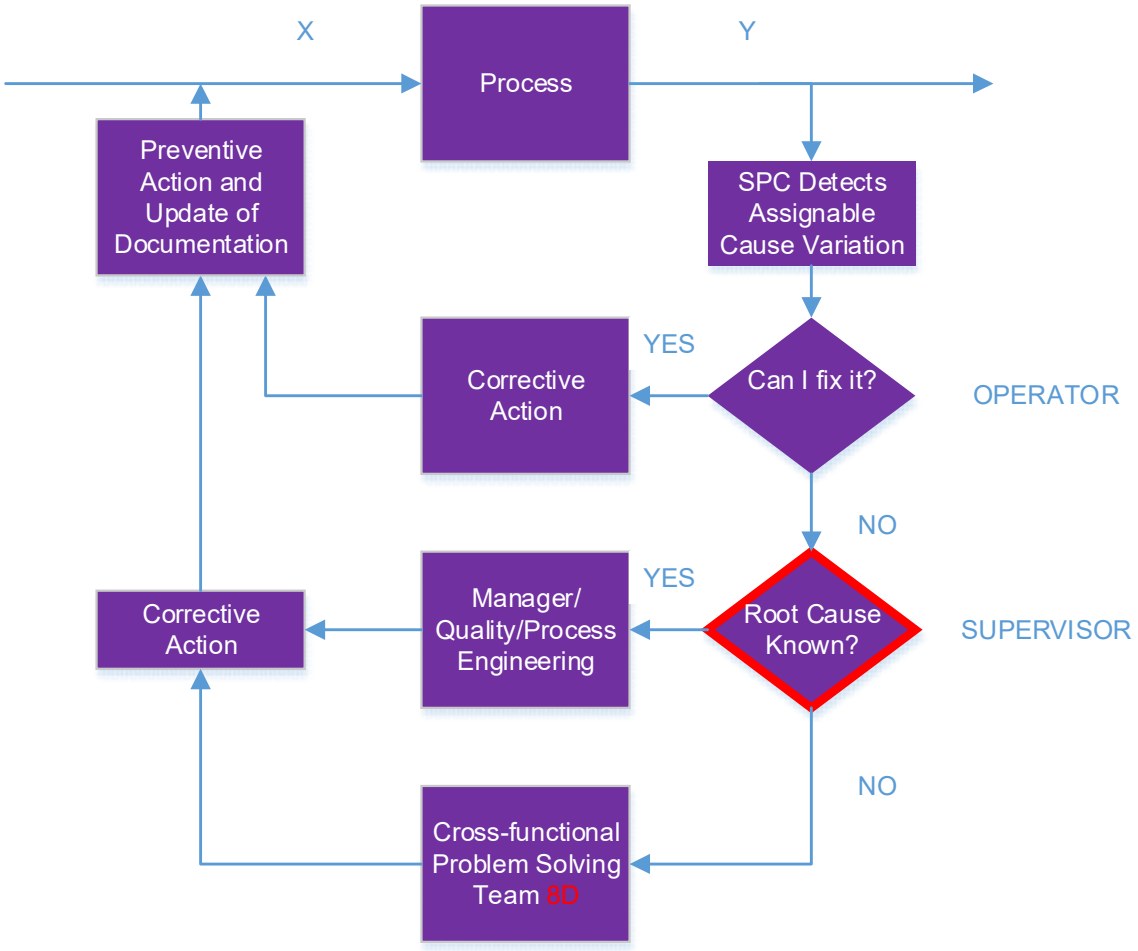


Figure 80: Graphical illustration of the out-of-control action plan for rapid problem solving

The problem addressed in Appendix H progresses through 8 steps of problem-solving and illustrates how the method is implemented. In this method the issue of metal contamination in one of the products was addressed with a corrective and preventive action put in place once the root cause was established. The response to the issue should be immediate with a monitored action plan set in place once the problem has been discussed.

5.10.1.4. Review documentation and process conditions

Upon completion of the problem-solving exercise and with the process returned to its natural state, the prerogative should now be to update the manufacturing documentation to incorporate all new failure modes and actions set in place, to prevent these issues form reoccurring.

If implemented successfully with a fully functional problem-solving methodology, SPC can improve process performance. The following section evaluates the process data before and after the implementation of SPC. Notably, when implemented correctly, SPC will improve the process; however, the success of the framework is based on the assistance and guidance provided during implementation and not the extent to which it improved the process performance.

5.11. Process performance

The following sections refer back to Section 4.3.10 and Section 5.8. The process performance is evaluated before and after the implementation of SPC.

5.11.1. Process stability

It is notable to mention that the process underwent a shift in its natural process limits with the aim of improving the centring of the process. This was done by making a fundamental process change prior to the implementation of SPC. The performance of the process prior to the implementation of SPC is consistent with the assumption that the process was running on the LCL with a large natural variation. Therefore the process had a greater probability of generating defective material. An attempt was made to address the variation by implementing SPC. Evaluating Figure 81, the overall standard deviation of the process was reduced from 0.093082 to 0.034789. This signifies a reduction of 63% for process variation. This is an isolation of the fundamental process change to adjust the process mean. Therefore, the p = 0.001, which, signifies a change in the process mean can be explained with the process shift in a positive direction. However, the standard deviation for the part-to-part variation was reduced by 11.3% and the overall process variation shows a reduction of 63%. Therefore, the process is more stable.

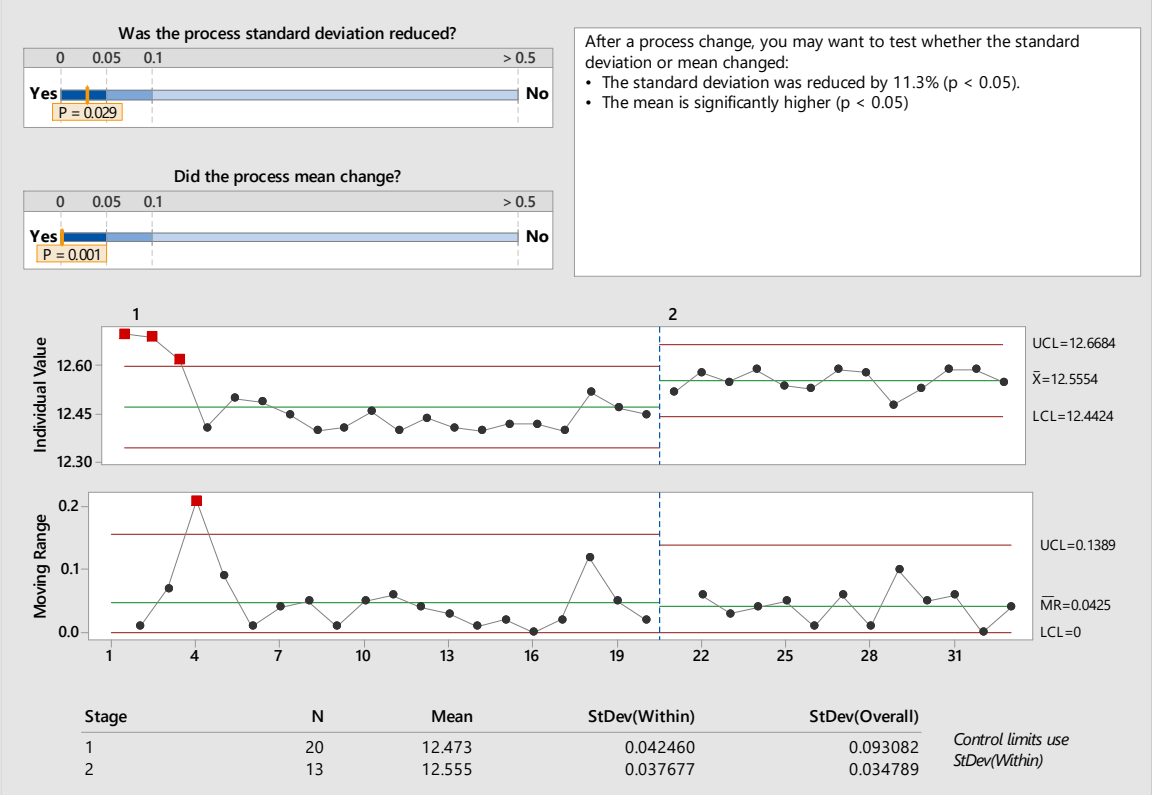


Figure 81: Before and after control chart of X_1

Following the confirmation of the process stability, the process capability is evaluated.

5.11.2. Process capability

The process capability evaluation estimates how well a specific dataset fits within the required tolerance band, a method widely employed to evaluate process performance. Complementing the above I-MR chart, the following diagram highlights the stability of the process. The capability of a process should only be evaluated once the process is within statistical control and stable. Figure 82 indicates that the process is more stable and normally distributed since the implementation of SPC.

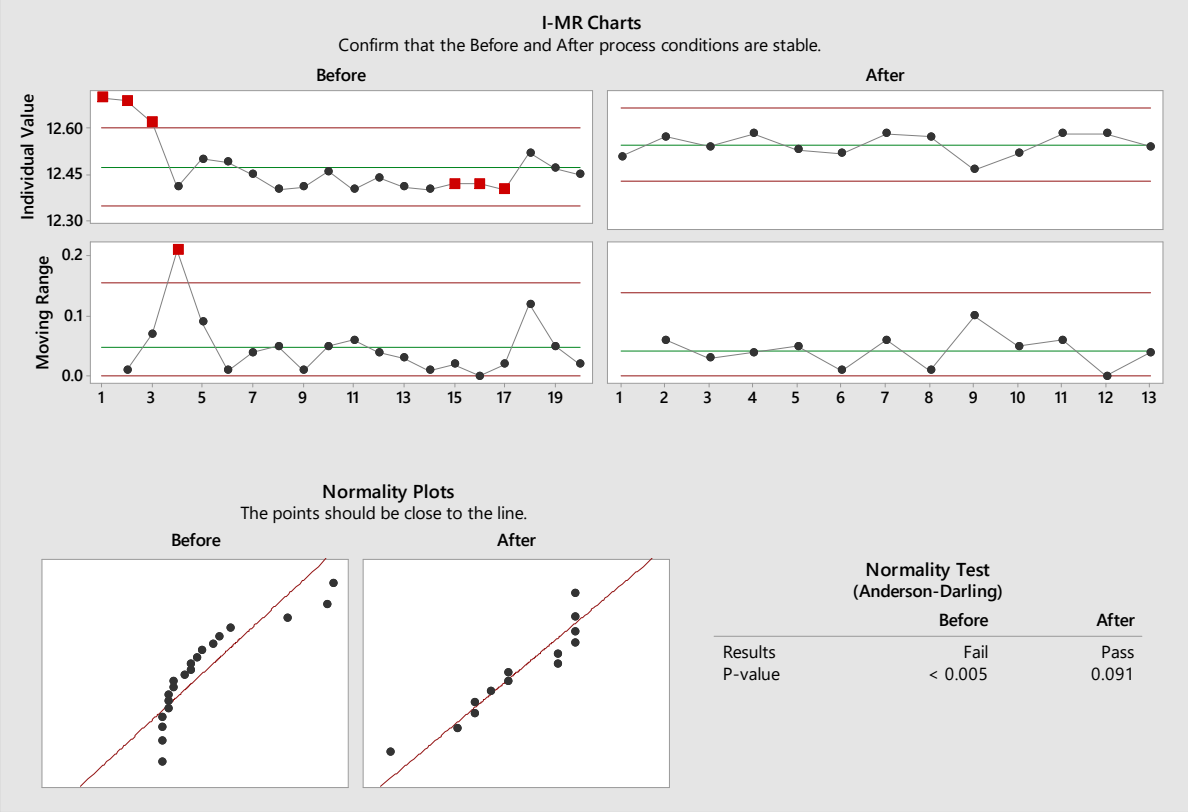


Figure 82: Diagnostic report for the before and after comparison for characteristic Y_1

The figures below evaluate the process performance before and after the implementation of SPC. Figure 83, Figure 84 and Figure 85 illustrate the before and after performance and highlight the difference in performance between the two datasets. It should be noted that the second dataset contains 13 measurements, compared against the initial dataset with 20 measurements. The process of SPC is continuous and the amount of data available was used for the evaluation. A larger sample size can be evaluated as time progresses. The improvement highlighted in Figure 85 is a reduction of 50% (32 – 16) of out-of-specification product. The defects per million opportunities were also reduced by 160 961 per million opportunities. A reduction in variation and DPMO indicates a positive process shift. This is supported with p = 0.029. However, the process centering deteriorated, expressing the effect of the fundamental process change on the performance. The dataset has a tighter spread, with most of the measurements on UCL control limit affecting the centering index.

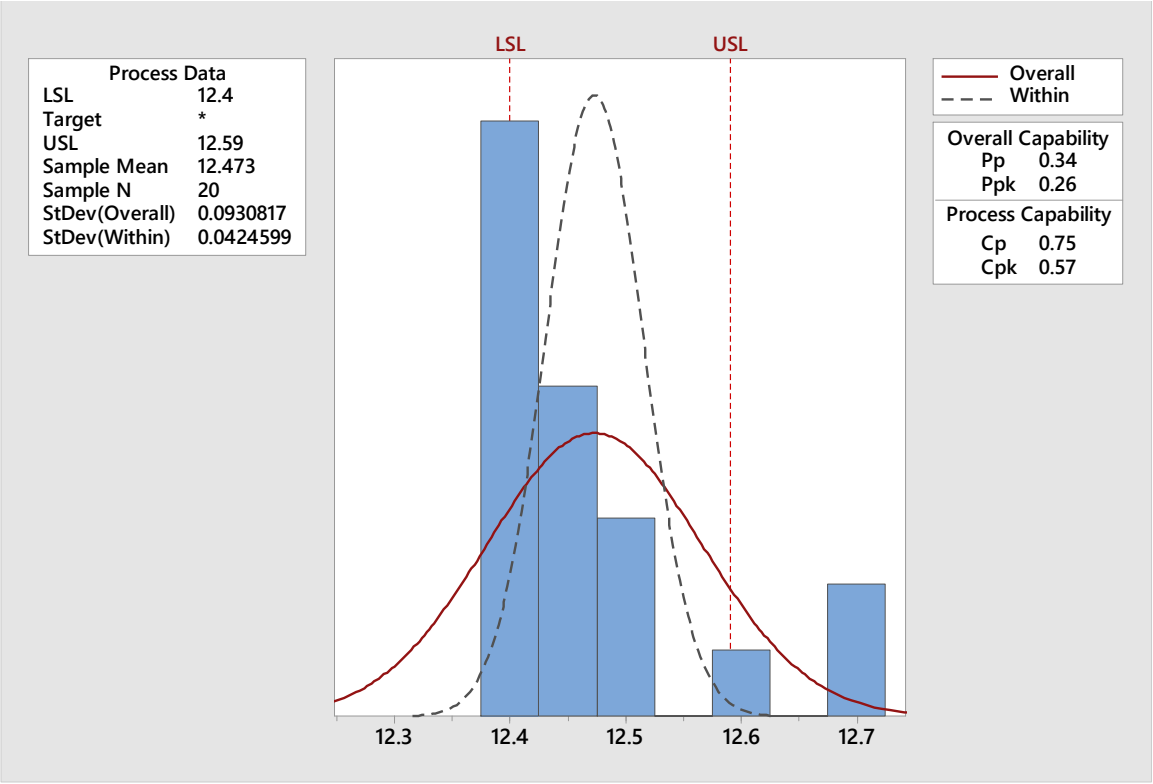


Figure 83: Distribution plot for character Y_1 before the implementation of SPC

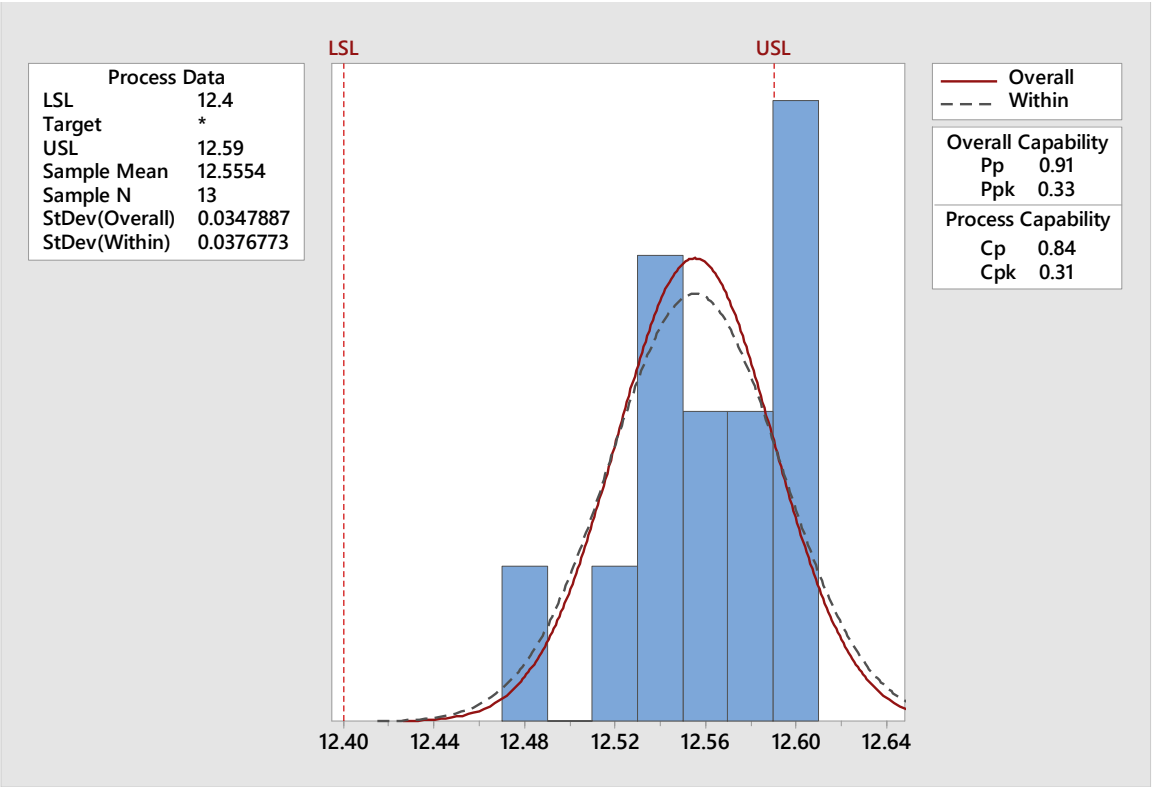


Figure 84: Distribution plot for character Y_1 after the implementation of SPC

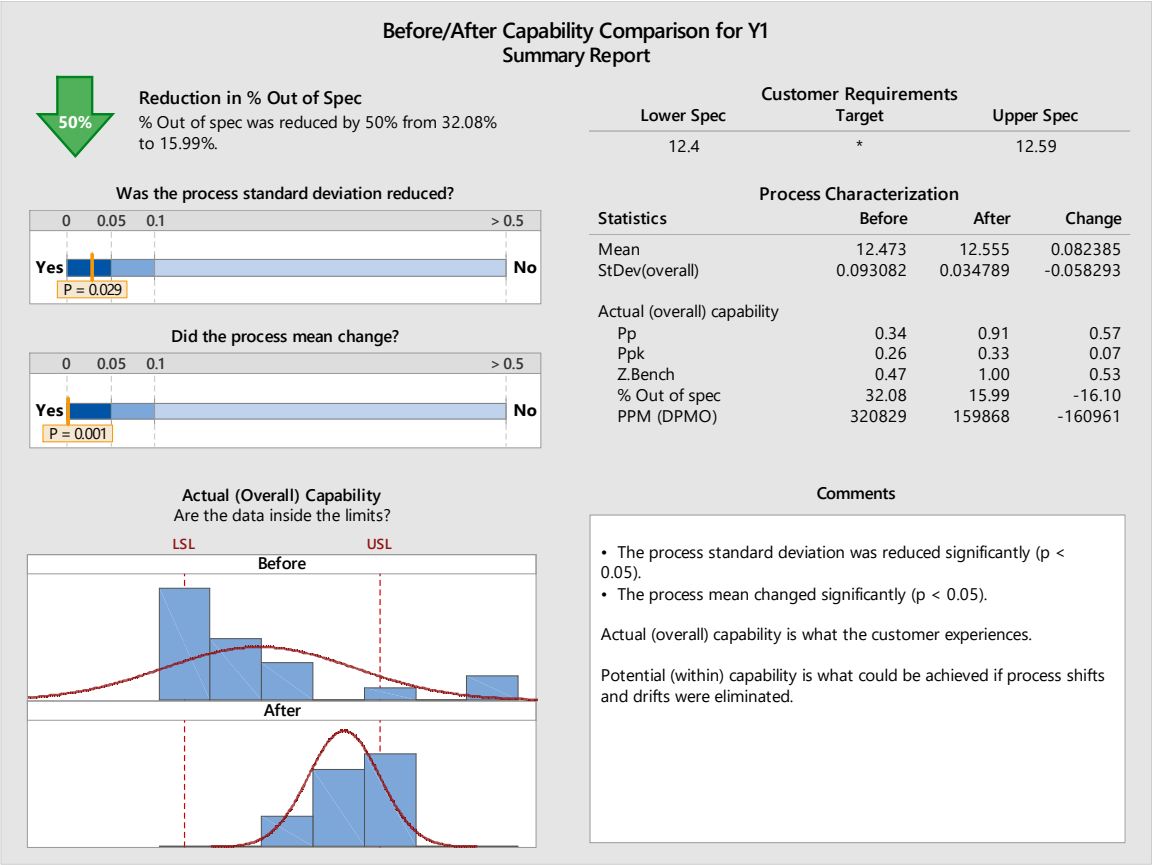


Figure 85: Process capability summary for the before and after for characteristic Y_1

5.12. Conclusion

Chapter 5 validates the proposed implementation framework by systematically progressing through each step proposed in the framework and providing detail on 'how to' implement each step. The Chapter illustrates the practicality of the proposed framework, relevant to SMEs and finally showcases the ability of SPC to reduce process variation when implemented correctly. This is supported by a reduction in process variation by 63% and a decrease in defects per million opportunities by 160 961 per million opportunities. The next chapter summarises and concludes the main findings of the research study.

Chapter 6 – Conclusion and recommendations

Quality is the degree to which a set of inherent characteristics or requirements, generally defined by the client or customer, is adhered to (ISO, 2015). Reducing process variation increases the probability of delivering a quality product to a client. Therefore, SPC was implemented with the intention to enhance this ability. A framework to support and guide the implementation of SPC was generated with the aim of reducing process variation, which may lead to a decrease in defects per million opportunities.

The previous five chapters evaluated and discussed literature relevant to SPC, identifying deficiencies and CSFs in published literature, developed a supporting framework for the implementation of SPC in SMEs and validated the framework as a case study, using action research. This was executed using the methodologies described in Chapter 3 to academically contribute to the domain of quality management and continuous improvement in a manufacturing environment.

The research study was strategically approached by moving from a general level to a specific case study using the methodology described in Chapter 3. Therefore, the research started by reviewing existing frameworks and theories focusing on the use of SPC in manufacturing. The author summarised the reviewed literature by identifying gaps and subsequently formulated a research question based on the deficiencies identified in literature. The framework was developed by incorporating different facets of the existing theory, coupled with experience in the field of quality management. The specific framework was then validated using a case study in a specific manufacturing company, grounding the proposed conclusions on experiences and demonstrated functionality of the framework, while trying to implement SPC.

6.1. Objectives of research study

The main research aim of this study was to *establish the best practice organizational and methodical requirements which have to be in place to effectively implement an operator friendly and sustainable SPC programme in a South African SME* by establishing *which factors contribute to the success of SPC deployment and how SPC can be implemented in an environment with limited resources.* Therefore, the primary objective of this study is the generation of an implementation framework which can support the sustainable deployment of SPC in manufacturing SMEs. The objectives and the relevant thesis chapters in which they are addressed are presented in Table 32.

Table 32: Summary of research objectives

	Objective	**Relevant chapter**
1	Critically review and analyse theory, tools and frameworks for Critical Success Factors (CSFs) for SPC implementation	Chapter 2
2	Critically review and analyse theory, tools and frameworks from other CI initiatives (Six Sigma, Lean)	Chapter 2
3	Identify deficiencies in published implementation frameworks and summarise the CSFs	Chapter 4
4	Address the deficiencies in existing implementation strategies and tailor the solutions for South African SMEs.	Chapter 2 & Chapter 4
5	Construct a framework for the effective and strategic implementation of SPC in chemical manufacturing SMEs, grounding the framework on the outcome of the reviewed frameworks.	Chapter 4
6	Critically review and analyse existing company procedures and data to establish SPC baseline	Chapter 5
7	Validate the model in the proposed environment as a case study using action research	Chapter 5
8	Evaluate the process performance before and after the implementation of SPC	Chapter 5

6.2. Research approach

The research methodology consisted of a systematic and random literature review, providing the platform to construct an implementation framework for the implementation of SPC in SMEs. This framework was validated in the case study environment of an SME with 110 employees and an annual turnover of less than ZAR400 000 million, using action research. The data collection involved the analysis of process parameters before and after the implementation of SPC. However, the primary validation involved the systematic progression through the proposed framework performing each step in the process environment and elaborating on the findings during that specific step. The methodology is explained in Chapter 3, which prompted the literature review in Chapter 2, generating the framework in Chapter 4, which is validated in Chapter 5. The following section summarises the main findings.

6.3. Summary of main findings

The main findings for this research study are derived from the: (1) literature review, (2) the framework development, (3) the framework validation and the (4) evaluation of process performance.

6.3.1. Literature review

The literature review was the fundamental base on which the complete framework was developed as 16 papers were reviewed for deficiencies and critical success factors.

Table 33: Summary of critical success factor ranking as sourced from literature

Ranking	CSFs	% articles containing CSF	Where incorporated in research study
1	Training & Education	81%	4.3.1,4.3.2 and 4.3.3
2	Management Commitment	69%	4.3.1 and 4.3.2
3	Teamwork	63%	4.3.4
4	Customer Focus	50%	4.3.6 and 4.3.7
4	Employee Involvement	50%	4.3.5, 4.3.4 and 4.3.12
5	Planning	44%	Chapter 4
6	Awareness	38%	4.3.1, 4.3.3 and 4.3.5
6	Employee Empowerment	38%	4.3.5 and 4.3.12
6	Integration into the Business Strategy	38%	6.3.3
7	Statistical Thinking	13%	Chapter 4 and Chapter 5

The table above ranks each critical success factor as they appeared in literature. Each CSF was integrated into the framework development and was illustrated in the validation of the framework to ensure a holistic approach to the implementation of SPC. This section of the research was aimed at addressing the research objective requiring the identification of factors having to be in place to implement SPC. The above aspects are all support functions of the main SPC tool and are generally addressed prior to the implementation or during the implementation of SPC. The most challenging aspect was the training and education of employees, therefore the author aimed at incorporating as much of the technical requirements into the implementation platform, such as control chart calculations and the generation of control charts. However, the employees were given training on these concepts. This was done for all employees interacting with the system to provide a secure platform to aid with decision-making and the ability to identify any issues which were not generated by assignable cause variation in the process (faulty calculation or Excel sheet).

Management commitment was easily obtained as the implementation of SPC is a desire, motivated by the failed previous initial attempt at implementing SPC. The integration into the business strategy was identified as crucial in literature and similarly in this research study. It was found that it is most effective to link SPC directly to customer requirements (product specification), supported by aspects of SPC integrated into all the manufacturing systems. The findings suggest that awareness, management commitment and training with regards to SPC, serve as strong motivational factors for easier acceptance of SPC by employees. Allowing employees the opportunity to understand the purpose of the implementation supported by management's commitment and an integrated system significantly increased the probability of acceptance and successful

implementation. Therefore management commitment is a major observed influence, which is broadly in line with the 69% of articles listing it as critical to the implementation of SPC (see Table 33).

An aspect that was not raised in the above table, but which was identified as a deficiency in most of the frameworks was the technical aspects of measurement systems analysis and process prioritisation. This will be discussed further below. Although statistical thinking was mentioned the least in these frameworks, this is one of the most critical aspects to educate the employees on as the concept of SPC is based on statistical thinking. Hence the emphasis on the above-mentioned concepts as their correct implementation is critical to successful deployment of SPC. Therefore, the concept of statistical thinking should be nurtured and embraced as it will greatly contribute to how quality is perceived (Grigg & Walls, 2007).

Table 34: Identified deficiencies of implementation frameworks

Author	Deficiencies	Where was it addressed?
(Ali, 1992)	× The checklist is not commissioned and provides no insight as to how it will be *implemented*. × Corrective procedures are mentioned, but *lacks problem solving* depth × No mention of *measurement system capability.*	Chapter 5 5.10 5.6
(Carter, 1993)	× Implementation model only focuses on the employees and software. *Lacks detail* in start to finish implementation plan or roadmap with a major gap in the 'how to'. × The implementation concept is stand-alone with no link to *problem-solving.*	Chapter 5
(Krumwiede & Sheu, 1996)	× Lack of detail in *product/process prioritisation* step × No mention of *measurement system capab*ility × No real detail on effectiveness of implementation, therefore no *real validation.*	5.5 5.6 Chapter 5
(Kumar & Motwani, 1996)	× No mention of *measurement system capability*. × The *problem-solving* actions and continuous improvement process are ill-defined and cannot be implemented with the amount of information provided	5.6 5.10
Donnell & Singhal, 1996)	× Lacks detail on how to *prioritise processes*. × No detail on how to determine *critical-to-quality characteristics* × No mention of *measurement system capability*	5.5 5.6
(Does et al., 1997)	× No *training* of employees is mentioned. × The methodological guideline has a very detailed overview, but *lacks technical depth* which should give the user a simpler guideline of what to do × Lacks *logical flow* of implementation steps.	5.4 Chapter 4 and Chapter 5 4.4
(Antony & Taner, 2003)	× Framework *not validated* with no guide on how to operationalise model.	Chapter 5

Author	Weaknesses	Where was it addressed?
(Noskievičová, 2010)	× Framework is *not validated* or actually implemented.	Chapter 5
(Vassilakis & Besseris, 2010)	× Stand-alone system that does not assist with *predictive identification of out-of-control points.* × Nothing mentioned on *training and education*.	5.8 5.4
(Kumar *et al.*, 2011)	× The framework does not explain how to *operationalise* the model. × The authors speak *of identifying* the best people *to train,* process and *project prioritisation*, but no plan is provided on identifying these requirements.	Chapter 5 4.3.5, 5.4 & 5.5
(Prajapati, 2012)	× Not very operationally friendly as nothing is mentioned with regards to *training and measurement system capability.*	4.3.5, 5.5 & 5.7
(Awaj et al., 2013)	× Although training is mentioned, very little is explained on *training and education*. × Very little is mentioned on *measurement system analysis.* × The application is more reactive than proactive, SPC is *not implemented in real time* but control charts are compiled for material already manufactured.	4.3.5 & 5.4 5.6 5.8
(Rantamäki et al., 2013)	× Model not feasible for *organizations of various sizes* as system is based on a highly computerised IT system. × Not *scalable.*	Chapter 5
(Sharma & Kharub, 2014a)	× Although Sharma and Kharub (Sharma & Kharub, 2014b) mention the lack of availability of a *step-by-step guide for the implementation of SPC* , they fail to better on this standing by providing a framework with a very high level approach. × SMEs do not have the *resources* to appoint a steering committee and a process action team as the resources will be utilised in the implementation of quality assurance and quality control and it will be difficult to stretch employees to take charge of a companywide project of this magnitude.	4.4 5.3
(Toledo et al., 2017)	× Developed framework does not seem functional nor is there any structure on how to implement the framework and its actions. × Responsibility for certain actions is entrusted to more than one actor in the framework. × *Framework does not contain problem-solving element or OCAP.*	Chapter 5 5.3 5.10

The above table illustrates the deficiencies identified in the published frameworks and where they were addressed in the research study. The table substantiates the holistic nature of the proposed framework, based on the research studies' attempts at addressing every identified deficiency and incorporating these deficiencies into the framework and as part of the validation.

Referring back to Section 2.15, arguably none of the reviewed articles presented a framework which could have assisted the quality manager with the previous implementation attempt of SPC as none of them contained the technical proficiency to really guide the user, specifically when addressing measurement systems analysis and process prioritisation. These two aspects, coupled with the proposed problem-solving methodology were the main outcomes of this research study.

6.3.2. Validation of framework as a case study

6.3.2.1. Framework validation in the case study environment

The framework validation was performed by following the prosed guideline and implementing SPC using the proposed steps. Key outcomes deduced from the validation are elaborated on below.

6.3.2.2. MSA

Measurement systems analyses incorporates statistical thinking, teamwork, customer focus, employee involvement, integration into business strategy and statistical thinking. Measurements systems analysis was applied on the analytical methods of the testing facility, the laboratory analyst and the evaluation of the control of the calibration procedure of the field instruments to guarantee precision and accuracy on all the measurements. Referring back to Table 34, Section 4.3.7 and Section 5.6, the approach for the MSA originated from an internal procedure, and is supported by AIAG (2010).

The measurement capability study on the instrument proved to have adequate sensitivity and sufficient discriminating power to test for different levels and grades of the product. The study offers evidence, using the precision-to-tolerance ratio, that the instrument contributes little to no variation to the overall process variation and is capable of returning accurate measurements when compared to the allowed tolerance of the measured characteristic (see Table 33).

The GRR results for the raw material testing system using Minitab®, suggested that repeatability contributes 31.55% (30 ≥ not acceptable) to the total variation with the GRR indicating a total measurement system variation of 33.78 %. The GRR also suggested a reproducibility of 12.06% (10 ≤ acceptable ≤ 30). This coupled with proper calibration procedures and execution concluded the MSA.

The findings are consistent with the current way of analysing the material as a sample is tested in duplicate and the average value returned as the measurement value of the material. The MSA also supports the notion of skilled analysts. The importance of the MSA was highlighted by various authors (see Table 12) as the criticality of an accurate and precise measurement not only links to quality in the proposed case study environment, but also safety. Therefore, an accurate measurement system is beyond critical to the operation.

6.3.2.3. Process prioritisation

Process prioritisation incorporates teamwork, customer focus, employee involvement, planning, integration into business strategy and statistical thinking. The lack of process prioritisation was evident in publications evaluated in Table 12. However, the method followed for process prioritisation (in this research study) may be applicable in any industry as the tools used to evaluate the data sets are easily accessible. During the validation stage the Pareto chart, process capability and multivariate regression analysis proved to be powerful tools when employed to identify poor process performance and parameters.

Referring back to Section 4.3.6 and Section 5.5, the model does not fit the dataset very well, as expressed by R-squared equal to 22, 9%. However, the acceptable p-value supports a causal relationship between the two datasets, the two datasets being inversely proportional with a decrease in X_1 generating an increase in Y_1 up until the point where Y_1 reaches a plateau. The model is good enough to generate a range for which a specific section of X_1 values will generate a specific Y_1. Given the nature of the process, this is acceptable as the repeatability of the manufacturing process is good but not exact, as the nature of the raw material (a commodity) cannot be controlled and influences the process. In summary, by controlling the X_1 the chances of generating a more consistent product is higher. Therefore, the study offers evidence and support that the process prioritisation method followed can be beneficial if implemented correctly, which will contribute to the correct implementation of SPC.

6.3.2.4. Problem-solving – Out-of-control action plan

Problem-solving incorporates training and education, management commitment, teamwork, employee involvement, employee empowerment, planning, statistical thinking and integration into business strategy. The detailed approach to problem-solving goes against the frameworks proposed by the authors in Table 12 (Ali, 1992; Carter, 1993; Toledo *et al.*, 2017; Wang & Zhang, 2008); but is consistent with research and methods proposed by Abdul Halim Lim *et al.*(2015), Noskievičová (2010), Rantamäki *et al.*(2013) and Romdhane *et al.*(2017). The method used for the problem-solving section runs parallel with methods proposed by Noskievičová (2010) and Romdhane *et al.* (2017). Subsequently, the tools employed were derived from internal procedures, but are supported by Alexa & Kiss (2018), Krajnc (2012) and Kumar & Adaveesh (2017) for the 8D methodology and Ford (2011) and Kulkarni & Shrivastava (2013) for the FMEA. The tools are effective and quick as illustrated by the FMEA (see Table 31) and can be systematic and exhaustive as proposed by the example in Appendix F.

6.3.2.5. Process performance

The process performance aspect of SPC highlights the optimisation power of the tool itself. This is seen by a reduction in variation of 50% (standard deviation – see Figure 85) and an increase in process capability from 0.72 – 0.85 (see Figure 83 and Figure 84). The final results for the increase in process capability do not

conform to the requirement (C_p – 1.11), therefore the process is still not capable and requires additional work in order to improve the process performance. SPC managed to reduce the variation, but not significantly increase the process performance. The organisation should employ DOEs to find the exact operational tolerance for the process and then employ SPC to control the variation in the process to a minimum.

Focusing on the enhanced process performance and the significance of this on the effective implementation of SPC, the improved process performance does not entirely endorse the effectiveness of the framework when implementing SPC. It suggests that the implementation was done correctly as all the steps followed during the implementation contributed to an effective SPC system, therefore reducing the overall variation of the process. *The study provides evidence that the framework presented in Figure 32, supported by the framework validation and steps proposed in Chapter 5; identified and incorporated the factors, which contribute to the best practice organisational and methodical requirements to effectively implement an operator friendly and sustainable SPC programme in a South African SME and guides the implementation in an environment with limited resources. This research was intended as guidance for the implementation of SPC in a SME manufacturing environment, which this study offers as illustrated in Chapter 4 and 5 and specific to organisations classified as SMEs (see Table 7).*

No refinement was required to the framework presented in Figure 33.

A core requirement of this study was to integrate the method into the business processes. The section below will detail aspects attempted in the organisation to embed SPC and problem-solving into the business processes.

6.3.3. Sustainability – organisational integration of SPC

The organisational integration of SPC is mentioned at random in sections above. However, this concept may add value to the organisation if methods are established and utilised to ensure that SPC is integrated and embedded into company procedures and daily operation. The following section will discuss methods used in the case study environment to integrate the use of SPC.

The organisational integration describes the attempt to entrench the elements and values of SPC into the business processes of the organisation to ensure that a continuous improved culture is cultivated and continuously improved. This is governed by employee exposure to different facets related to SPC but also in an attempt to instil a 'Total Quality approach'. A common issue at manufacturing facilities is that elements such as manufacturing documentation, with the intention of assisting operators and business systems has no real platform to be used by the operator, therefore it serves as a paper exercise. The sampling and inspection plan and FMEA are examples of these cases. By utilising SPC correctly and ensuring the integration of certain

aspects into the process of the organisation, the attempt at embedding SPC into the everyday operation can be achieved.

In all the reviewed frameworks and articles a common appearance was made by the OCAP. No implementation method was provided. Using the FMEA (see Section 2.8) as the basis of the OCAP guarantees that one of the stand-alone documents is utilised and also contributes to employee empowerment. The following aspects can assist with further integration of such concepts into the daily operations and they also highlight certain elements which are already included but not recognised.

- Check sheets – These are sheets use to collect data for SPC. Also called log sheets or 'dailys' and are already part of the control room culture.
- Fishbone and Pareto Charts are integrated into the problem-solving platforms of the company. Tools such as 8D and '5 Why' problem-solving incorporate these elements.
- Process Qualifications are performed to evaluate the capability and performance of the processes. The process qualification utilises histograms and capability evaluations to qualify a process. MSAs are also performed to ensure precise and accurate results.
- The FMEA as the basis of the OCAP.
- Sampling and Inspection Plans and Manufacturing Instructions are tools which support the SPC programme and can be used as a baseline when assessing for the possible cause of a process deviations as these documents are used to standardise sampling and inspection points for all the processes (see Table 38).
- SPC has to be integrated into the business processes of the organisation. This was done by integrating SPC and the application of statistical and data-driven decision-making, a cultural shift, focusing on data and the application of statistics to guide decision-making on product and process quality. The stigma of viewing SPC as just control charts should be terminated, therefore the need for a cultural shift.
-

The integration was gradually done by integrating statistical quality control and statistics into the following procedures and processes of the organisation:

- Lab method and instrument qualifications – Measurement system evaluation using the range method.
- Sampling and control plan
- Process qualifications – Process capability studies.
- Calibration of equipment to minimise and eliminate bias, linearity and ensure stable measurements.

The research study applied cross function tools for the aim of continuous improvement. SPC, MSA, FMEA and the 8D problem-solving methodology were applied (see Figure 86), coupled with the gaps identified in the literature review to provide a holistic approach to SPC implementation and continuous improvement.

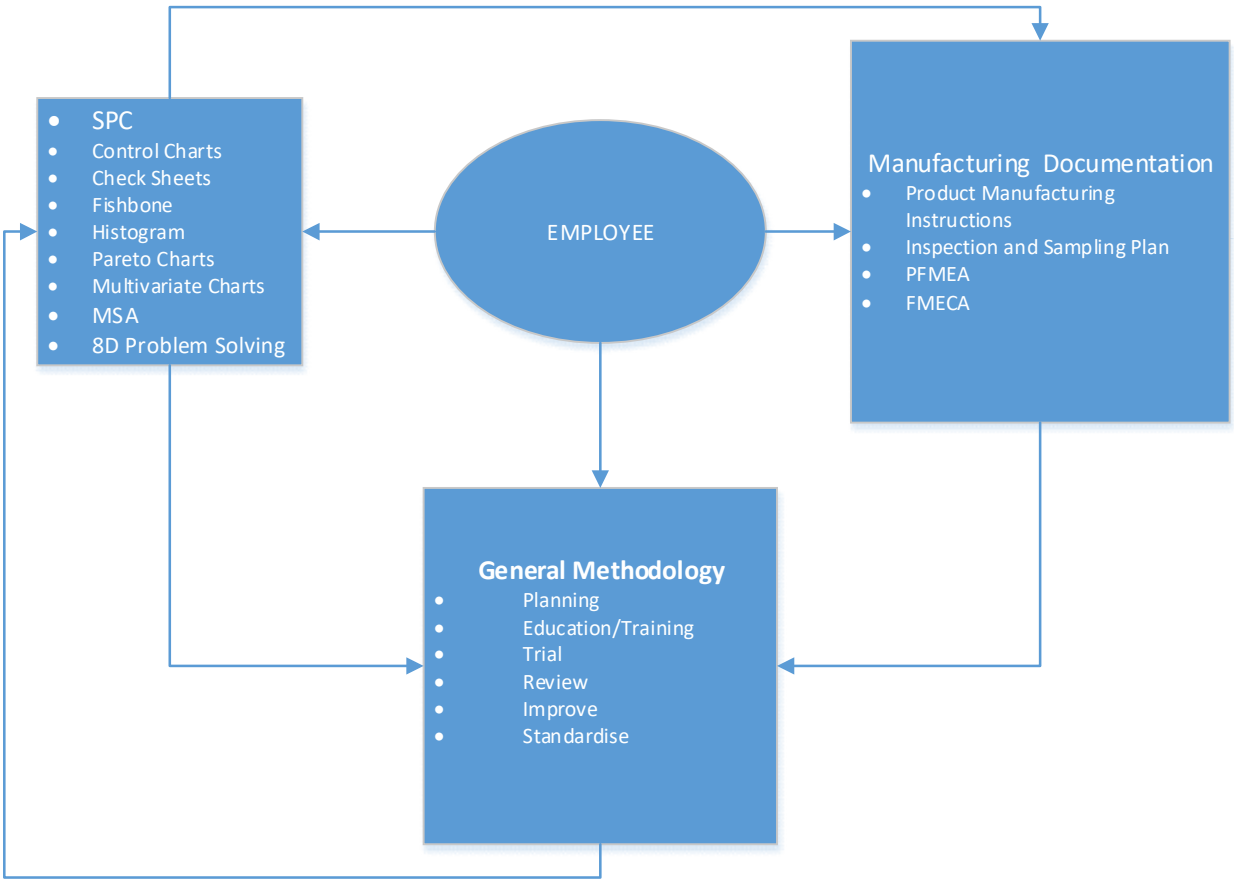


Figure 86: Proposed structure for organisational integration of SPC

Source: Adapted from (Yusof & Aspinwall, 2000)

6.3.4. Problems

A major problem, which had to be addressed and agreed on was the decision-making authority of operators. The general line of authority at the facility demanded that every process deviation or complication had to be reported to facility supervisor to manage and deal with. For SPC to be successful and active the control room operator should have delegated authority in order to use the OCAP structure. This frees up the supervisor and provides a platform for employee empowerment. The reaction time to problem will be faster.

The decision on an implementation platform which would be suitable and practical was a challenge, as there are very advanced software tools on the market at costly prices. The challenge originates from desiring low-cost solutions linking with old facilities.

6.4. Limitations

The maturity level of the company and openness of the organisation to continuous improvement affects the diffusion rate of SPC. Different organisations will interpret and implement SPC differently, however the proposed framework may assist with standardising the implementation of SPC as the methods used are applicable to all industries.

The development of the framework did not follow a set guideline for construction, but was developed based on concepts and factors identified as critical during the review process The concepts were seen as important by the author and deficiencies were identified based on the author's understanding of the concepts and experiences in the field of quality management and SPC.

This study based the framework development on specific articles sourced from literature. There are many articles, books and reference manuals which deal with statistical process control and statistical quality control which may have been overlooked due to the nature of the systematic and the random review. The study only used sources which were seen as relevant to the specific research topic.

The validation of the framework was performed at one facility and analytical testing facility at a chemical manufacturing entity based in the Western Cape province of South Africa. Different facilities, industries and even fields of manufacturing may have returned different outcomes. The validation was also executed at a facility with a specific operational culture. This aspect could limit the applicability of the findings to other facilities or industries.

The process prioritisation step utilised correlation research to identify causal relationships between characteristics. The method does not concretely prove that one characteristic causes a change in another. Therefore, a method such as DOE may be more suitable to identify an exact relationship between two characteristics. However, the methods applied are widely used and acceptable with a proven record of practicality.

The sample size of the dataset can influence the results. Therefore, the outcome of applying the framework to a different process will not mirror the results achieved in this study. Different processes, characteristics and sample set sizes will return different results guiding the implementation in a different direction.

The study made use of Shewart I-MR control charts to fit the sampling frequency and data type. Control charts are selected based on the data type, sampling frequency and magnitude of shifts within the dataset.

CUSUM EWMA, P and U charts, to mention a few, may be used if applicable and may produce a different outcome to the one achieved in this research study.

6.5. Recommendations and future work

The study contributes to the domain of continuous improvement, quality management and SPC by attempting to address gaps identified in existing literature publications and addressing these matters with simple implementation guidelines. The proposed framework can be tailored to address unique organisation complexities in order to enhance the relevance to the organisation.

The proposed framework utilised Shewart charts. As mentioned in the literature review, a small trial can be performed on the data used, to evaluate the use of CUSUM charts and their capability of identifying small process changes. However, these charts are more complex and difficult to interpret making the application of them in a SME environment very impractical. However, the research would be beneficial to the organisation and can focus on finding simpler methods of training employees to use and interpret CUSUM and EWMA charts.

Design of experiments is a more definite way of causal relationship identification and can be pursued for a more exact outcome.

The lack of publications in South Africa relative to SPC is evident. Therefore, future research could employ surveys to South African organisations to estimate the level of SPC implementation.

The framework constructed was implemented in a single facility in the case study environment. The validation was also limited to a manufacturing entity. Further studies could focus on multiple case studies deployed in a variety of industries to further tailor the framework or to generalise the concept for varied industries. The concept of SPC is well known, but the effective application of SPC is not well established.

The validation of the framework used participatory action research. Another level of framework validation is the DELPHI technique or the use of surveys distributed to subject matter experts.

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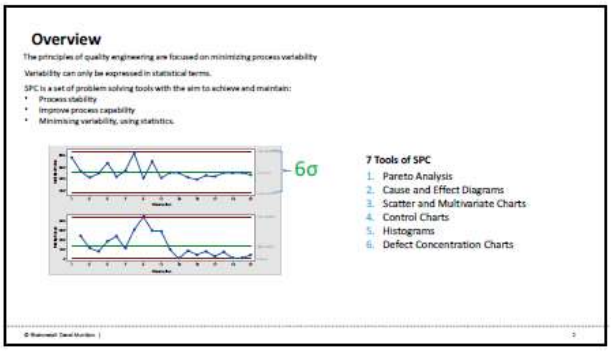
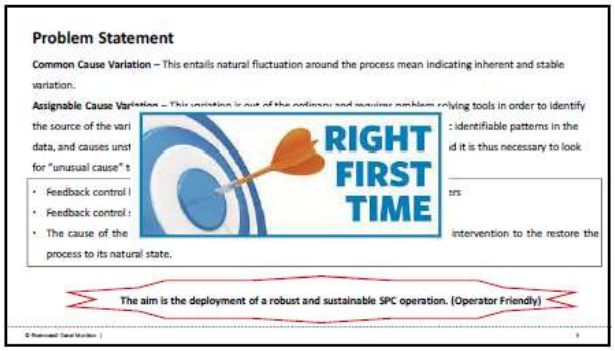
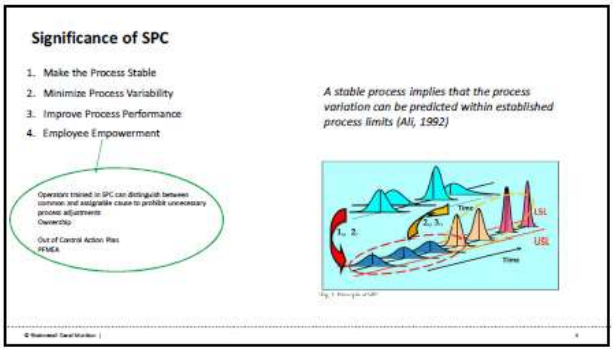
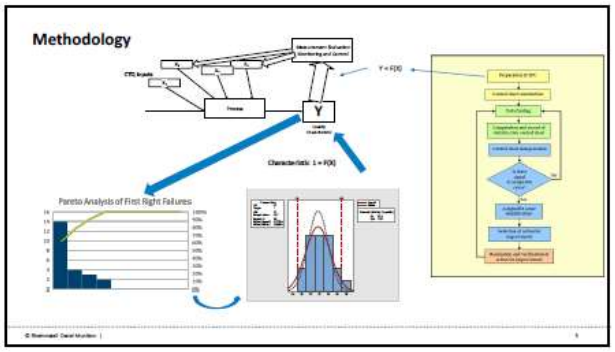
Appendix A: Management commitment and awareness presentations

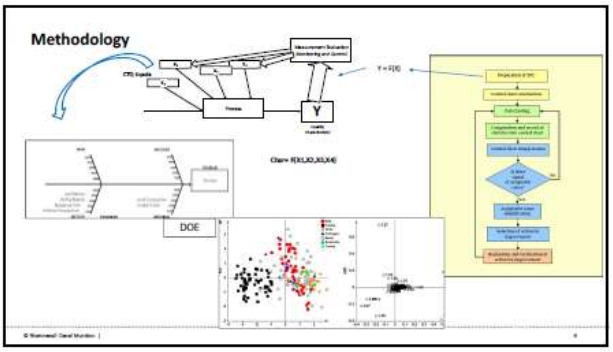
Pre-management commitment and awareness

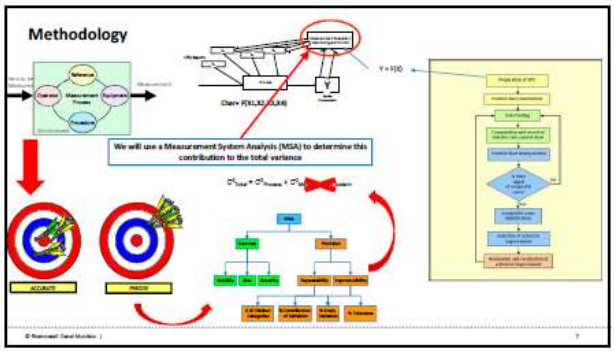


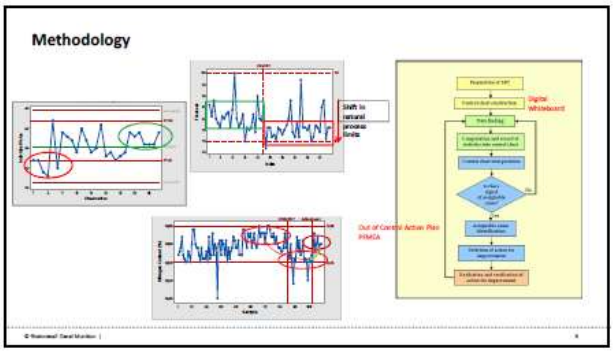


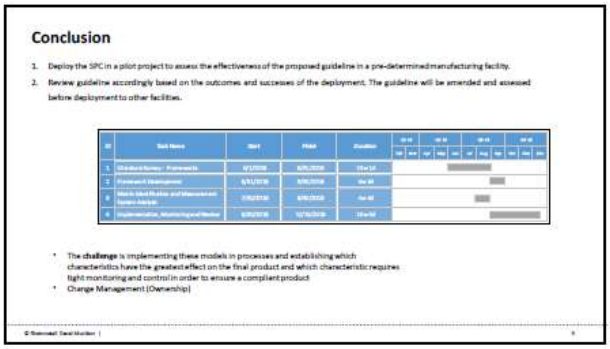




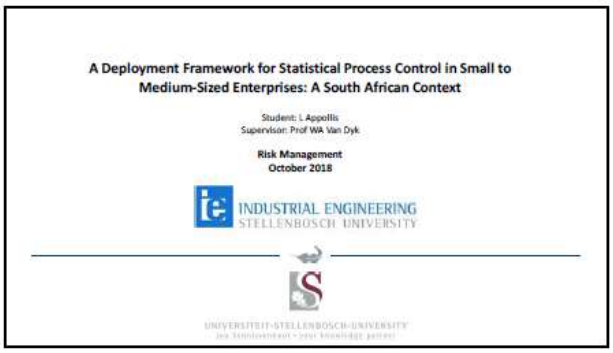


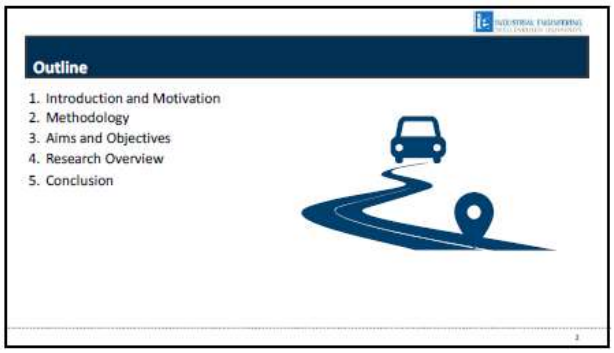


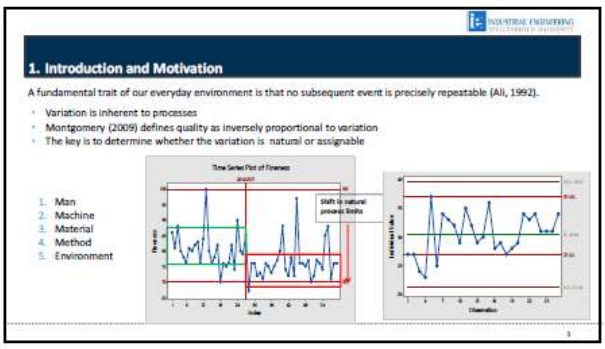


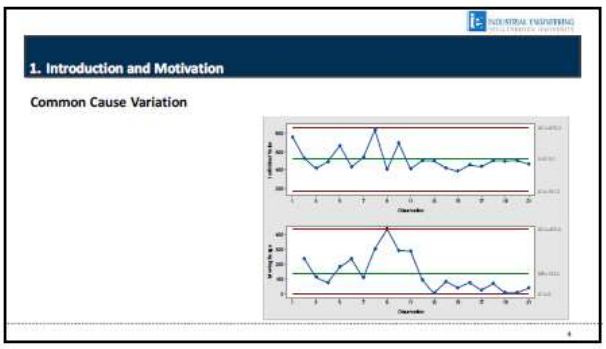


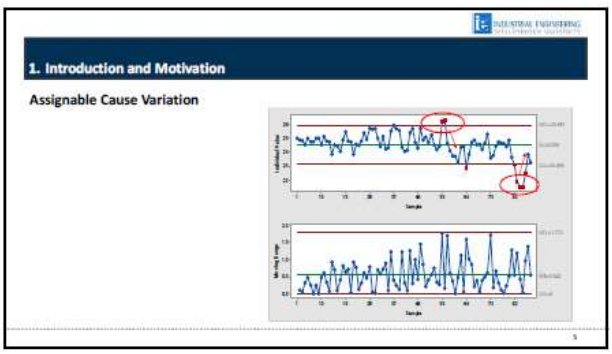
Colloquium presentation in support for management commitment









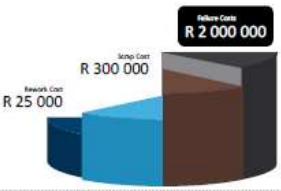


1. Introduction and Motivation

" Productivity increases with quality as rework and scrap is minimised, thereby saving time and money " (Deming, 1986)

Excessive Process Variation and Unstable Processes leads to

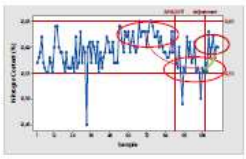
- Increased Defect Rate
- High Cost of Quality
- Decreased Productivity
- Employee Morale



1. Introduction and Motivation

How do we handle variation ?

- Feedback control loops are built into logic control systems to regulate process parameters
- Feedback control systems cannot distinguish between common and assignable cause
- The cause of the variation will however not be removed and it is still up to human intervention to the restore the process to its natural state.



1. Introduction and Motivation

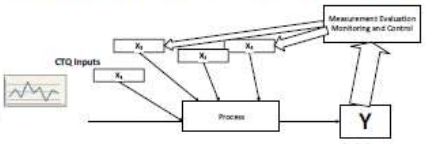
The principles of quality engineering are focused on minimizing process variability

Variability can only be expressed in statistical terms.

Statistical Process Control is a set of problem solving tools with the aim to achieve and maintain process stability and improve process capability by minimising variability, using statistics (Montgomery, 2009 ; Škulj, Vrabič, Butala & Sluga, 2013)

$Y = f(x_i)$

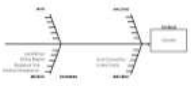
(x_1) Man
(x_2) Machine
(x_3) Material
(x_4) Method
(x_5) Environment

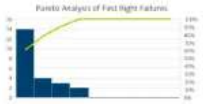


1. Introduction and Motivation

7 Tools of SPC

1. Pareto Analysis
2. Cause and Effect Diagrams
3. Scatter and Multivariate Charts
4. Control Charts
5. Histograms
6. Defect Concentration Charts
7. Check Sheets



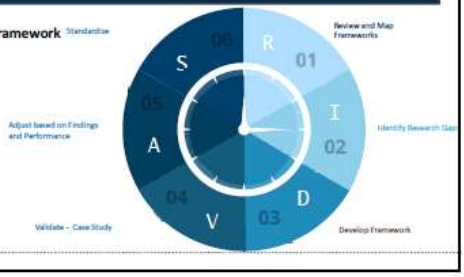


2. Aims and Objectives

- The primary objective is to develop a " How to " implementation framework for SPC for an environment with limited resources.
- The challenge is the deployment of a robust and sustainable SPC operation that is operator friendly.
- Ultimately to minimize variation of the critical to quality characteristics.

3. Methodology

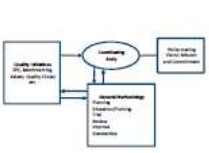
Implementation Framework



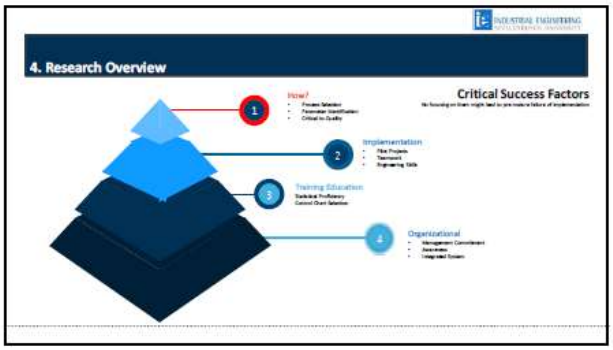
4. Research Overview

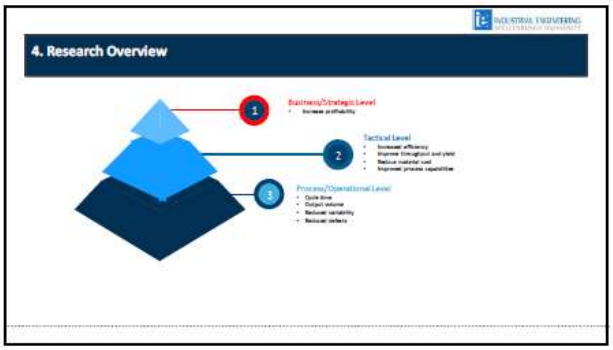
Implementation Framework

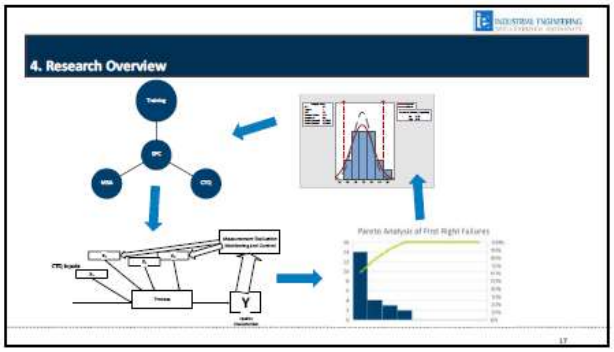
4. Research Overview

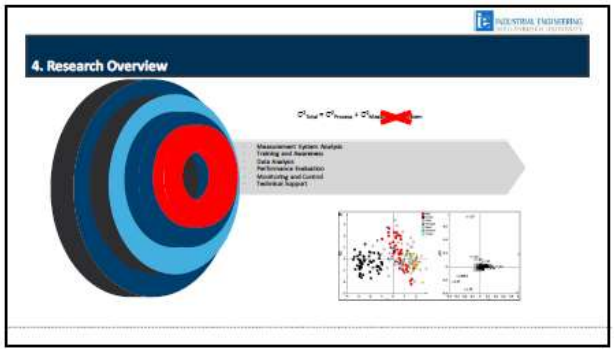


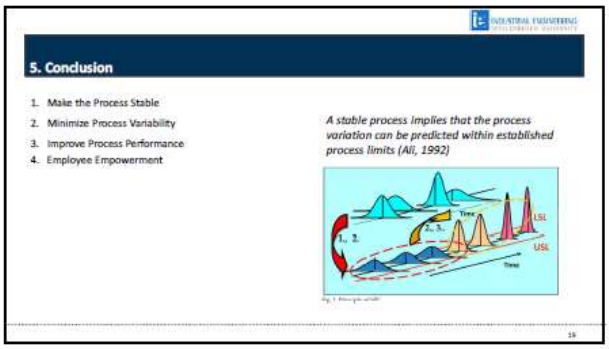
(Antony & Taner, 2003) (Yusof & Aspinwall, 2000) (Donnell & Singhal, 1996)

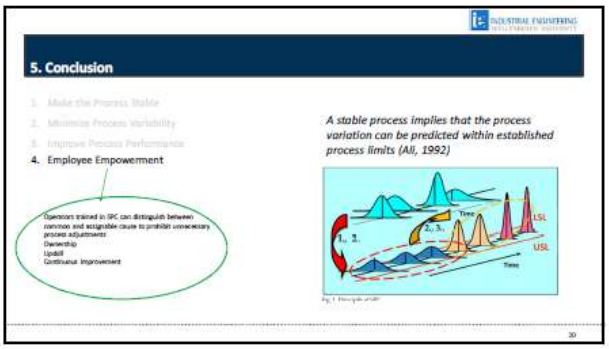


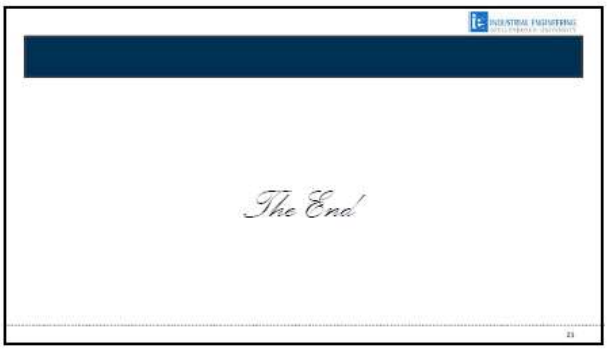












Appendix B: Document approval

Table 35: Document validation

DOCUMENT VALIDATION

	Name	Function	Signature	Date
Original Author	xxxxxxxxxx	Quality Engineer		
Reviewed	xxxxxxxxxx	Document Control		
	xxxxxxxxxx	Plant Manager		
	xxxxxxxxxx	Process Manager		
Approved	xxxxxxxxxx	Quality Manager		

DOCUMENT CHANGE RECORD

Rev	Change Note	Date	Pages	Paragraph / Description

Appendix C: MSA – Calibration certificates

File Number A5-V

TEST RESULTS

% UNIT	SCALE mA	INPUT Ω	AS FOUND OUTPUT mA	AS FOUND DEVIATION mA	AS FOUND % ERROR OFS	AS LEFT OUTPUT mA	AS LEFT DEVIATION mA	AS LEFT % ERROR OFS
0	4	100	3.98	-0.02	0.125%	3.98	-0.02	0.125%
10	5.6	103.9	5.59	-0.01	0.062%	5.59	-0.01	0.062%
20	7.2	107.79	7.2	0	0.000%	7.2	0	0.000%
30	8.8	111.67	8.79	-0.01	0.063%	8.79	-0.01	0.063%
40	10.4	115.54	10.39	-0.01	0.062%	10.39	-0.01	0.062%
50	12	119.39	11.99	-0.01	0.062%	11.99	-0.01	0.062%
60	13.6	123.24	13.6	0	0.000%	13.6	0	0.000%
70	15.2	127.07	15.2	0	0.000%	15.2	0	0.000%
80	16.8	130.89	16.8	0	0.000%	16.8	0	0.000%
90	18.4	134.7	18.4	0	0.000%	18.4	0	0.000%
100	20	138.5	20.01	0.01	0.063%	20.01	0.01	0.063%

As Found : Pass ☑ As Found : Fail ☐

Corrective Action : Recalibrate ☐ Corrective Action : None ☑

As Left : Pass ☑ As Left : Fail ☐

Figure 87 Example of calibration certificate valid for 6 months after calibration date

File Number A5-A

TEST RESULTS

% UNIT	SCALE kPa	INPUT kPa	AS FOUND OUTPUT kPa	AS FOUND DEVIATION kPa	AS FOUND % ERROR OFS	AS LEFT OUTPUT kPa	AS LEFT DEVIATION kPa	AS LEFT % ERROR OFS
0	0	0	0	0	0.000%	0	0	0.000%
10	60	60	65	5	0.833%	65	5	0.833%
20	120	120	125	5	0.833%	125	5	0.833%
30	180	180	185	5	0.833%	185	5	0.833%
40	240	240	243	3	0.500%	243	3	0.500%
50	300	300	300	0	0.000%	300	0	0.000%
60	360	360	360	0	0.000%	360	0	0.000%
70	420	420	420	0	0.000%	420	0	0.000%
80	480	480	480	0	0.000%	480	0	0.000%
90	540	540	540	0	0.000%	540	0	0.000%
100	600	600	600	0	0.000%	600	0	0.000%

As Found : Pass ☑ As Found : Fail ☐

Corrective Action : Recalibrate ☐ Corrective Action : None ☑

As Left : Pass ☑ As Left : Fail ☐

Figure 88: Example of calibration certificate valid for 6 months after calibration date

Appendix D: Failure modes and effects analysis

Table 36: Example of failure modes and effects analysis template

No	Component / function	Purpose Requirement	Potential Failure Mode(s)	Potential effect of the failure		Classification	Causes	Corrective action		Sev	Occ	Det	RPN	Recommendations	Responsibility and Target Completion date	Actions Taken	New Sev	New Occ	New Det	New RPN	Status[%]
				Manufacturing	End user			Detection	Prevention												
1	Mixing	To mix raw materials in a fixed ratio in order to obtain a homogenous mixture	Raw Material Ratio incorrect	Too high Comp A (or low Comp B) causes increased sensitivity of mixture	Safety issues downstream, customer complaint	MB	Control System Failure; Faulty Scale; Blockages in Line, Transport Nitrogen falls away during displacement	Sampling as per documentation, Alarm for Nitrogen pressure, Visual inspection of blockages	Scheduled Maintenance and Calibration; Training as per PMI; Blowing of transport lines to clear blockages	5	2	5	50								0
			Heterogeneous Mixture	Component A settling out - safety concern, possible failure to meet product specification	Safety issues downstream, customer complaint	C	Low Nitrogen Pressure; Incorrect sparging time by operator	Alarm for Nitrogen pressure	Training; Stock Control Enforced;	9	2	3	54								0

Appendix E: 8D Problem-solving

Initiator :	Date :	Affected department :	Linked CAR Number:	Number of previous occurrences :
John Doe	14-May-19	Operations	NCR_188_19	
Problem Driver :	**First occurrence :**	**Monitored since :**	**Target completion date:**	
Jane Doe	10-May-19	10-May-19		

Cross-functional Team:

Quality Engineer	Process Manager	Plant Engineer	Maintenance Manager	Plant Supervisor
Jnr Process Engineer	Chemical Engineer	Artisan	Maintenance Supervisor	Operator

☑ Management	☑ Quality	☑ Operator	☑ Supervisor	☑ Maintenance
☐ Warranty	☐ Technical	☐ Warehouse	☑ Manufacturing	☐ Other

2a. Problem Title

Contamination of batch #03-0119 of material caused damage of transfer pumps.

2b. Description / Sketch / Photo of the Problem

Upon routine inspection of after manufacturing batch **#03-0119**, it was found that the pump impeller and internal volute was damaged. This triggered the inspection of PUMP 2, PUMP 3 and the Disintegrator. All 4 pumps had internal damages, supporting the suspicion of metal contamination of the batch.

3. Short term counter measures (Immediate containment within 24 hrs)

	WHAT	WHO	BY WHEN
1	Pump (PUMP 1) was opened	Plant Manager	09-05-19
2	All the pumps were opened and checked for damage	Plant Manager	10-05-19
3	Material Quarantined	Quality Engineer	10-05-19
4	Process was stopped - Packaging of product postponed	Plant Manager	10-05-19
5			
6			
7			

Problem Driver:

Due date:

10-05-19

Signature: (Initiator)

Breakpoint: The possibility of metal contamination in the product

☐ Stop production	☐ Alert on-line personnel/insp.	☑ Isolate defective stock	☐ Deviation
☐ Additional skilled resources	☐ Record all reworked units	☐ Method to ID reworked stock	☐

4a. Root Cause Analysis

Involve the members of the cross-functional team to do a structured root cause analysis by using the 5WHY and / or the FISHBONE method.

Responsible:

(Problem Solving Team)

Sequence of events that led to the non-conformance
PUMP 2, PUMP 1, PUMP 3 and the Disintegrator was damaged. **Why?**
Metal contamination of the batch. **Why?**
Bearing failure of TANK 101 Stirrer/ Bearing seizure. **Why?**
Emulsification of grease and failure of external rubber coated seal. **Why?**
Corrosion. **Why?**
Water vapour (Tank contents consist of 50°C contaminated water) ingress into the bearing housing, corroding the bearing casing over time. *(Vapour got into the bearing housing, condensed and emulsified the lubricant, the bearing casing started corroding over time causing the seal to be damaged.)* **Why?**
Oil seal performance inadequate in preventing water vapour from entering bearing housing.
FISHBONE DIAGRAM -

as above

Additional Notes:

(1) Pump came back from supplier - Pump installed Friday 26 April 2019 – Pump was fine upon installation
(2) 3rd of May – No abnormal sounds in the previous run
(3) Sound identified on Monday 6 May 2019 by an Operator at TANK 101 - one squeak in the specific period he was there while the team was mixing a batch of Facility α– Couldn't notice anything abnormal – as time went on – he informed Team leader and the team leader informed the Plant Manager
(4) Tuesday the same sound was identified – Manager told supervisor and he can confirm the squeaking sound was still present - 5 mixes were made on Tuesday – Plant Supervisor informed Artisan to please check the gearbox
(5) Thursday Morning upon opening the pump, damage was noticed 9 May – PUMP 1 – Pump check due to previous water leaks and possibility of increased product build up in this pump.
(6) Operator noticed the rust marks.
(7) Friday – Artisan opened the Disintegrator and noticed the damage to the pump, rust – Reported this to a superior
(8) Damage to PUMP 1 impeller and volute - This triggered the inspection of all the other pumps.
(9)Metal shaving stuck into Disintegrator
(10) Only PUMP 4 has not been opened – No damage to the pump - Pump started up for sample Thursday morning and Friday morning

4b. Root Cause Analysis (… continued)

Define further activities:

	CHECK	WHO	BY WHEN (Due)
1	Check Stirrer Gearbox	Maint. Supervisor	13-05-19
2	Confirm bearing type and configuration	Maint. Supervisor	16-05-19
3			

Finished on:

Signature: (Initiator)

Result:

The Bearing failed and subsequently the oil sealed also failed which caused ingress of metal into the product. One oil seal is inadequate, which subsequently resulted in bearing seizure due to corrosion (water vapour bypassed the oil seal and condensed inside the bearing housing).

☐ Imported part Quality ☐ Transport damage ☐ Poor Process ☐ Poor Design

☐ Not as per specifications ☐ Equipment/Tool problem ☐ Operator error ☑ Other:

5. Permanent Corrective Actions

Responsible: (Problem Driver)

	WHAT	WHO	BY WHEN (Due)
1	Replace bearing and oil seal of TANK 101 stirrer	Plant Manager	31-05-19
2	Maintenance inspection on bearings	Maint. Supervisor	31-05-19
3			
4			
5			

Finished on: **28-05-19**

Signature:

☑ Mistake Proofing ☐ Design Change ☐ Single point lesson ☐ Other

6. Monitoring of Effectiveness

Initiator / Trigger:

1 Perform condition monitoring, on TANK 101 stirrer bearing - Inspect after first run and follow up with an inspection schedule.

Due date:

Finished on:

Signature: (initiator)

7. Preventative Actions

Can this solution be adopted for preventive action in other areas, systems or processes? ☑ **Yes** ☐ **No**

Responsible: (Problem Driver)

Due date: 31-05-19

	Where	Preventive Action	Communicated to
1	H4 - TANK 101 Stirrer	Two oil seals to be installed in-series. The purpose of the secondary seal is to reduce the risks of any water ingress or moisture which can cause emulsification of grease that may result in complete bearing seizure. This MOD (oil seal plate) is designed such that if any bearing failure occurs in future, all pieces of metal that may pass through the first seal are trapped or contained.	Maintenance manager, MOC Committee
2	H4 - TANK 101 Stirrer	Establish a detailed maintenance schedule for TANK 101.	Maintenance manager, MOC Committee

Finished on:

Signature: (Problem Driver)

Did any of the following processes fail? (If so, these should be corrected):

☑ Risk analysis ☐ FMEA ☐ Control Plan ☐ Other

8. Conclusion

Bulk of equipment on site has passed its useful life and therefore requires a change in its maintenance strategy (i.e. preventative, predictive, and run-to-failure). The planning, scheduling and execution of maintenance (through a work management process) to ensure success of business operations is very critical. Plant operations and maintenance shares responsibility in this regard. It is hereby suggested that Maintenance Management and Plant Management (Operations) meet frequently (every 3 months) to discuss short term maintained goals (in-line with set strategy) to ensure optimum equipment/machine performance as well as opportunities for autonomous maintenance. It is also critical to note, if an operator hears, see's or feel anything that he/she deems unsafe, it is the operator's right to STOP the operation then report it to management for their review in accordance to SHE best practices.

Team and Individual Feedback and Recognition

☑ Communicate findings to relevant employees ☑ Recognise the efforts and results of team / individuals

Initiator :	**Quality Manager:**	**Plant Manager:**	
Signature:	**Signature:**	**Signature:**	

Appendix F: Raw data for control charts

Table 37: Analytical lab results used for generation of control charts

Date in	Tank	Batch	Level	Comp1	Comp2	X_1	SG
01/02/2019	121E	3	90%	61.40	22.42	16.18	1.692
04/02/2019	121D	2C	90%	61.68	22.09	16.23	1.690
04/02/2019	121C	4A	96%	61.26	22.63	16.11	1.691
04/02/2019	122C	5	90%	61.62	22.26	16.12	1.690
06/02/2019	122C	9	92%	61.58	22.02	16.4	1.689
06/02/2019	121D	7C	5%	61.35	22.34	16.35	1.690
06/02/2019	121C	8	90%	61.21	22.45	16.34	1.690
14/02/2019	122C	11	91%	61.73	22.06	16.21	1.689
18/02/2019	121C	13	95%	61.60	22.01	16.39	1.690
27/02/2019	121D	16	91%	61.41	22.53	16.06	1.685
27/02/2019	121F	15	90%	61.18	22.80	16.02	1.684
27/02/2019	121C	14A	59%	61.07	22.69	16.24	1.681
27/02/2019	121f	15a	90%	61.78	22.44	15.78	1.686
27/02/2019	121d	16a	91%	61.35	22.64	16.01	1.684
27/02/2019	122c	17	90%	61.52	22.67	15.81	1.686
27/02/2019	121f	15aR	89%	61.77	21.99	16.24	1.681
27/02/2019	121d	16aR	50%	61.36	22.37	16.27	1.681
10/04/2019	121D	46	84%	61.23	22.47	16.29	1.689
11/04/2019	122C	43D	40%	61.28	22.52	16.20	1.690
11/04/2019	121C	45A	90%	61.21	22.55	16.24	1.690
11/04/2019	121F	44F	100%	61.34	22.47	16.20	1.699
11/04/2019	122C	47A	90%	61.03	22.62	16.36	1.688
11/04/2019	122C	49	90%	61.04	22.83	16.13	1.688
11/04/2019	121C	48A	90%	61.17	22.50	16.33	1.689
23/04/2019	122C	50		61.46	22.38	16.16	1.685
25/04/2019	121E	51B	68%	61.26	22.59	16.15	1.689
25/04/2019	121C	52C	20%	61.46	22.31	16.24	1.691
25/04/2019	121F	53C	60%	61.42	22.26	16.32	1.691
25/04/2019	121C	56	90%	61.62	22.21	16.18	1.690
25/04/2019	122C	54A	35%	61.52	22.13	16.35	1.689
03/06/2019	121D	71	89%	59.65	23.77	16.59	1.685
03/06/2019	122C	72	95%	60.03	23.32	16.65	1.684
05/06/2019	122C	72A	96%	59.36	23.89	16.75	1.684

Date in	Tank	Batch	Level	Comp1	Comp2	X_1	SG
05/06/2019	122C	72B	65%	59.37	24.10	16.53	1.688
05/06/2019	121F	73	90%	60.25	24.22	15.53	1.692
05/06/2019	121C	74	90%	59.33	24.58	16.09	1.689
05/06/2019	121F	73A	90%	59.64	24.18	16.18	1.690
05/06/2019	121E	75	90%	59.21	24.60	16.19	1.688
05/06/2019	121C	74A	90%	59.35	24.22	16.44	1.689
05/06/2019	121F	73B	50%	59.40	23.06	17.55	1.677
05/06/2019	121E	75A	92%	59.67	23.84	16.49	1.685
05/06/2019	122C	76	90%	59.56	23.99	16.45	1.687
05/06/2019	121E	77	90%	59.40	24.20	16.41	1.683
07/05/2019	121E	57A	93%	61.07	22.59	16.36	1.689
07/05/2019	121E	57B	96%	59.58	23.90	16.52	1.683
07/05/2019	122C	58A	96%	59.91	23.69	16.41	1.684
14/05/2019	121D	59	95%	60.14	24.26	15.61	1.680
14/05/2019	121E	60	91%	59.83	23.86	16.31	1.685
14/05/2019	121D	59A	95%	60.22	24.08	15.71	1.688
14/05/2019	121D	59B	92%	59.85	23.60	16.56	1.685
16/05/2019	122C	62	47%	60.39	23.21	16.40	1.682
16/05/2019	121F	61	87%	60.45	23.65	15.90	1.684
20/05/2019	121D	64	89%	60.62	22.66	16.73	1.689
20/05/2019	121E	63	88%	60.34	22.55	17.10	1.695
21/05/2019	121D	64A	95%	59.62	24.32	16.07	1.686
21/05/2019	121E	63A	93%	59.76	24.56	15.68	1.688
21/05/2019	121E	63B	95%	59.88	24.16	15.96	1.680
27/05/2019	121D	66	91%	60.13	24.14	15.73	1.690
27/05/2019	122C	65	90%	60.50	22.43	17.07	1.683
27/05/2019	121D	66A	89%	59.83	23.95	16.22	1.688
28/05/2019	122C	65A	91%	59.87	23.72	16.41	1.688
29/05/2019	121E	67	90%	60.70	24.25	15.05	1.694
29/05/2019	121F	68	90%	59.82	24.04	16.14	1.690
29/05/2019	121D	67A	92%	59.68	24.22	16.10	1.689
29/05/2019	121E	69	90%	59.65	24.16	16.21	1.689
29/05/2019	122C	70	96%	59.78	24.01	16.21	1.690

Appendix G: Sampling and inspection plan

Table 38: Sampling and inspection plan

Line No.	Location	Items or Process to be Sampled or Inspected	Characteristic to be determined or Process Parameter to be inspected and Measurements	Class	Frequency	Sample Size	Test or Inspection Responsibility	Specification / Requirements	Method	Record	Action for Non-Conforming Product
Sam-1	51 F	Raw Material	Full Analysis	MB	Every batch	500g batch composite	Laboratory	7600-2020-06211XX	SLMEX 400	COA	Reject, Identify and store to prevent unintended use
Ins-1	59 C	Raw Material	COA	MB	Every Batch	N/A	Plant Manager/Supervisor	7600-2020-06211XX	Visual	File	Reject, Identify and store to prevent unintended use
Ins-2	51 C	Raw material transfer line	Magnet		Daily	N/A	Operator	111400-311100211XX	Visual	Check Sheet-OPS-082	Reject, Identify and store to prevent unintended use
Sam-2	57 F	Component 1– Road Tanker	Full Analysis	MB	Every Batch	500 ml	Laboratory	7600-2010-04711XX	SLMX 1047	COA	Reject, Identify and store to prevent unintended use
Ins-3	59 C	Component 1	COA	MB	Every Batch	N/A	Plant Manager/Supervisor	7600-2010-04711XX	Visual	File	Reject, Identify and store to prevent unintended use
Sam-3	Raw Material Tank Farm	Component 2-TK 124 A	Component 2 `Specific gravity	m	After Receipt	500 ml	Laboratory	111400-311100211XX	SLMX 1046	Check Sheet-079 Lab report	Reject, Identify and store to prevent unintended use
Sam-4	Raw Material Tank Farm	Component 1 – TK 126 A	Component 1 Specific gravity	m	After Receipt	500 ml	Laboratory	111400-311100211XX	SLMX 1047	Check Sheet-079 Lab report	Reject, Identify and store to prevent unintended use
Sam-5	Raw Material Tank Farm	Raw Material	Component 1 Component 2 X_1	MB	Every Batch	500 ml	Laboratory	111400-311100211XX	SLMEX 1053	Check Sheet-080 Check Sheet-088 Lab report	Reject, Identify and store to prevent unintended use