A Study on Statistical Process Control (SPC) in Pharmaceutical Contract Manufacturing: Potential Determinants of SPC Implementation Success

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Abstract

Many organisations in New Zealand are still unfamiliar with Statistical Process Control (SPC) or how to implement it successfully, even though SPC has been widely used in other countries such as Japan, with great success. The potential of SPC has been underestimated in most cases, especially in the Pharmaceutical industry that share some common ground with SPC (e.g. measurement and analysis). It is not just control charts that make SPC successful. A control chart is just a tool (and a useful one at that) being used in the practice of SPC. There are some critical factors or enablers of successful SPC implementation. The context of this study is pharmaceutical contract manufacturing (PCM). The aims of this research are to identify a suitable SPC programme for PCM companies, identify enablers of successful SPC implementation, and to understand how these enablers cause quality improvement.

A single case study was designed to verify the applicability of SPC. The research confirmed the suitability of a specific six-step SPC implementation approach mentioned in the literature. SPC was found to be a suitable technique for identifying and understanding process variation in PCM. The case study findings are useful to quality practitioners as well as PCM companies contemplating on implementing SPC. Regarding theoretical contributions, the researcher developed two theoretical models from extant literature and both models were empirically tested using survey data collected from 76 respondents using the state-of-the art in multivariate latent variable path modelling. The model test results showed that top management commitment has both a direct effect as well as an indirect effect on quality performance through other SPC/TQM enablers. The results also showed that soft factors of TQM/SPC are significantly more influential than hard factors of TQM/SPC in achieving quality performance. While this is nothing new, one thing that is novel in this research is the way researcher modelled hard and soft factors of TQM/SPC to estimate how much more important soft factors are than hard factors, in achieving quality performance. The limitations of the study and suggestions for future research have been provided at the end of this thesis (Chapter 6).

Acknowledgements

This research would not have been possible without the support of some key people. First of all, I would like thank my husband Joe for patient reviews of this thesis and supporting me through love and care, which kept me going in spite of my busy day job. I must also thank my employer, especially my manager Satish, and colleagues who helped me in numerous ways including patronising with me in my case study and quantitative data collection.

Heartfelt thank you to my academic supervisor Dr Nihal Jayamaha for advising me at various stages of the research and providing me invaluable feedback on my outputs. Nihal has provided technical guidance by directing me to refer to appropriate literature and software. Many thanks for his endless encouragement and advice. I would also like to thank Professor Nigel Grigg for supporting me and for looking at my work independently.

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List of Acronyms

APIs	Active Pharmaceutical Ingredients
AVE	Average Variance Extracted
BP	British Pharmacopoeia
CAGR	Compound Annual Growth Rate
cGMP	Current Good Manufacturing Practice
CI	Confidence Interval
CMB	Common Method Bias
CSFs	Critical Success Factors
DMM	Deming Management Method
DRIP	Data Rich/ Information Poor
EFA	Exploratory Factor Analysis
EFQM	European Foundation for Quality Management
FDA	Food and Drug Administration
HTMT	Heterotrait-Monotrait
IP	Indian Pharmacopoeia
JP	Japanese Pharmacopoeia
KMS	Knowledge Management Systems
LSL	Lower Specification Limit
NCEs	New Chemical Entities
PCA	Principle Components Analysis
PCM	pharmaceutical Contract manufacturing
PDSA	Plan-Do-Study-Act
Ph.Eur	European Pharmacopoeia
Ph.Int	International Pharmacopoeia
PLS	Partial Least Squares
SEM	Structural Equation Modelling
SPC	Statistical Process Control
TQM	Total Quality Management
USL	Upper Specification Limit
USP	United States Pharmacopoeia

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Chapter 1 INTRODUCTION

1.1 BACKGROUND

With the rapid development of global economic integration, external linkages are deemed important for consistent growth of manufacturing enterprises as they can obtain essential resources (certain physical goods and capabilities) from their partners through cooperation to sustain competitive advantage (Hagedoorn, 1993; DiMasi, Grabowski, & Hansen, 2016). Furthermore, Sánchez-González and Herrera (2015) emphasized the importance of external cooperation for overcoming the obstacles for innovation.

Over the past 10 to 15 years, there has been a shift in Pharmaceutical manufacturing toward broader use of the third-party network in the manufacturing of NCEs (new chemical entities) for clinical trials and commercial APIs (active pharmaceutical ingredients). This is mainly caused by an increase in cost pressures within the Pharmaceutical industry. (McWilliams et al., 2018). As the market becomes increasingly competitive, the quality of products becomes a unique differentiation opportunity to gain competitive advantage (Block, Kohn, Miller, & Ullrich, 2015; Porter, 1980). This in turn makes a direct impact on the development and growth of the organization.

One advantage of outsourcing is that a company can enter their target market more quickly, with less risk and more flexibility (McWilliams et al., 2018; Taylor, 2015). The pharmaceutical contract manufacturing (PCM) industry is known for the variability in raw material quality, diversity of processing techniques and typically, low volume of batch production. The main goal of any PCM company is to provide pharmaceutical products with the best quality at the lowest price possible, within agreed time frames for the customers (Taylor, 2015). The PCM market is highly fragmented. Not only must PCM companies be continuously meeting the requirements set by the customer (e.g. product specification), but they must also go above and beyond their normal call duty to exceed customer

needs and expectations, in order to stay competitive in the market. This may come in the form of being a quality leader, cost leader or a highly responsive supplier. Hence, products need to be manufactured with the right balance of quality, cost, speed, and productivity (Fuller, 2015; Han, Porterfield, & Li, 2012).

In a PCM company or otherwise, non-conformance to specifications or defects means that the product does not meet the customers' requirements. The cost of non-conformance is significant as conducting re-work will result in spending more resources such as raw materials, labour and time, which will increase the cost and reduce the profit (Evans & Lindsay, 2013). In many cases, customers will demand compensation from their suppliers for non-conforming products, which significantly reduces the profit margin of the supplier (the PCM Company). This will also negatively impact on the reputation of the supplier and confidence of the customers. Non-conformance is caused due to excessive variation of a key quality characteristic (e.g. weight, solubility) whilst manufacturing. Reducing these variations will improve product quality and increase profit (Hoerl & Snee, 2012; Makrymichalos, Antony, J, Antony, F, & Kumar, 2005). However, individual variations during different processes are often overlooked, and defects are developed due to accumulation of those variations. Inspecting defects at the end of the process is very costly, because it is too late to take corrective action (Deming, 1986). As discussed above, the consequences of shipping non-conforming product can be significant in terms of customer dissatisfaction and supplier profitability. Moreover, inspection does not improve quality because inspection does not to provide any insights on the causes for excessive variations.

Having a process that is behaving consistently well (i.e. high process capability) will improve product quality and continual monitoring of process variation and taking prompt remedial action when needed (i.e. a potential assignable cause being present) is needed for continuous improvement (Robinson, Audibert, & Zenda, 2000). This can be achieved through Statistical Process Control (SPC). SPC reduces variability by being able keep the variability within tolerance limits specified by the customer. The translates into fewer defects (or defective items), less rework, and decreased cost of poor quality (Montgomery, 2012).

1.2 STATISTICAL PROCESS CONTROL

SPC is a statistical-based management proactive consisting tools and techniques used within an improvement-based philosophy, such as Total Quality Management (TQM) or Six Sigma (Lim, Antony, & Arshed, 2016; Uluskan, 2019). In the 1920s, Dr. Walter A. Shewhart's concept of using statistical methods to detect lack of control in processes was first introduced at Bell labs. This concept was developed based on the understanding of variation by applying statistical theory, and this is the basis for SPC (DeVor, Chang, & Sutherland, 2007). W.E. Deming, another famous quality guru, elaborated on the principles of SPC; he popularised SPC in the Japanese manufacturing industry in the 1950s. However, it was not until 1980 that the western manufacturing industry adopted SPC in their own applications (Kang & Kvam, 2011). From then on, SPC has become popular topic in the academia. In the article database Figure 1-1 depicts the number of yearly publications from 1980 to 2018 based on Scopus, when searched for the key word "Statistical Process Control" in the article title, abstract, or key words.

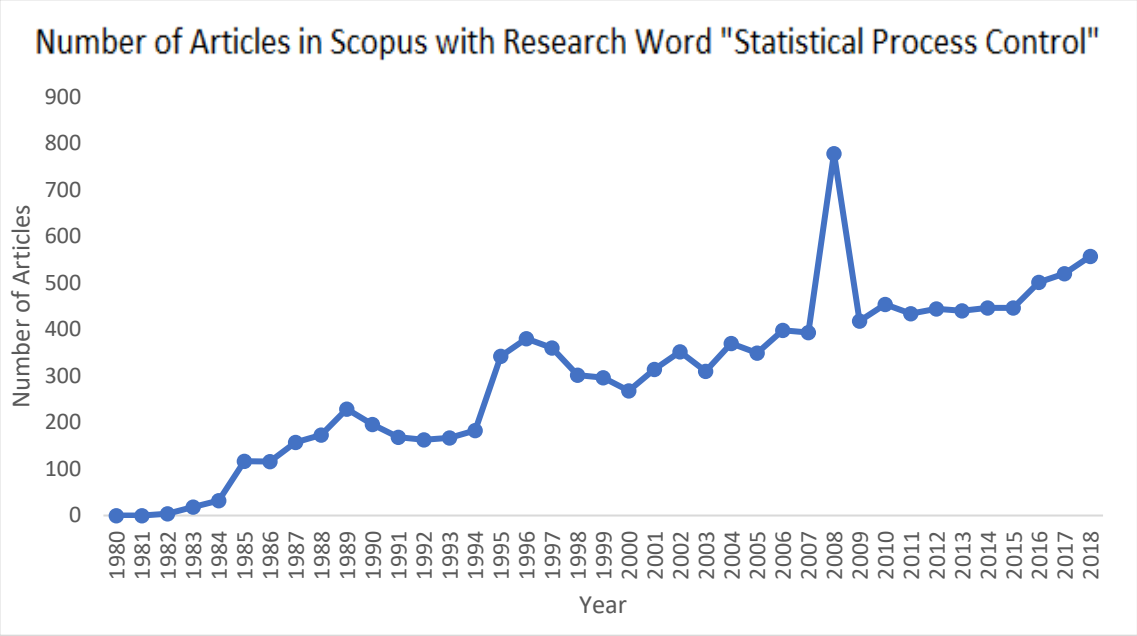


Figure 1-1 Articles found in Scopus containing the search word "Statistical Process Control"

SPC has been implemented in numerous sectors such as the healthcare, automotive, food, general services and the chemical industry. SPC has also expanded to other non-manufacturing sectors, including education and banking

(Rahman, Zain, Alias, & Nopiah, 2015). However, most researches on SPC seem to be generic and lack contextualisation (e.g. limited body of literature on how to operationalise SPC as a management approach to address the needs of the PCM industry). According to Ahmed and Hassan (2003), only few manufacturing companies use SPC meaningfully/effectively; according to them, most companies use only one or two simple SPC tools. To get the best results from SPC, a combination of tools and techniques need to be integrated within a management paradigm such as TQM. SPC has been criticised due to number of reasons: piecemeal application of tools and techniques that fail to detect defects and/or defective items effectively (e.g. detecting defects that occur whilst in use), potential risk of human errors made during application of SPC (e.g. errors in taking measurements and calculation errors) and time consuming efforts (Rahman et al., 2015).

This study sets apart from other SPC studies because, in this study, the researcher treats SPC as a management practice that underpins "statistical thinking" (Hoerl & Snee, 2012; Stamatis, 2003), which is a way of "action and learning", based on the premise that "understanding and reducing variation is the key to success" (ASQ, 1996). More details follow (Chapter 2). Consequently, tools and techniques become a baseline requirement to sustain quality improvement based on statistical thinking.

1.3 THE OVERARCHING RESEARCH QUESTION

One question that follows from the above is: "what would be an acceptable SPC programme for a PCM enterprise?". Other questions would be: "To implement such an SPC programme, what are the key determining or modifying factors?" and "what are the benefits of such an SPC programme?". Combining these three leads to the following overarching research question:

> *What are the benefits of implementing an acceptable statistical process control programme in pharmaceutical contract manufacturing?*

1.4 KEY DRIVERS FOR THE RESEARCH

Three things drove this research.

1.4.1 Resource Usage in Quality Improvement

Continuous quality improvement is a critical concept in contract pharmaceutical manufacturing. SPC is a well-established continuous quality improvement approach that focuses on reduction of process variability. However, Robinson et al. (2000) found that in some companies, although data is collected from manufacturing processes, these data are rarely been used meaningfully (e.g. reporting after the fact aggregate data are far less useful than processing live data to understand what is going on in the process. Stated alternatively, the manufacturing processes are poorly understood in most situations. This means a waste of resources and a forgone opportunity to gain benefits of continuous improvement, which involves such benefits as teamwork, respect for people, and empowerment, which are essential for quality improvement (Jayamaha, Wagner, Grigg, Campbell-Allen, & Harvie, 2014).

Since SPC is an effective scientific improvement method that many organisations fail to implement effectively, studying the implementation process by creating an SPC-based quality improvement platform mimics scientific experiments that the researcher is so used to; in essence designing a case study to learn SPC (the phenomenon of interest) by collecting quantitative and qualitative data associated with manufacturing processes in many respects parallels the researcher's day job. A related motivator was training to know what factors are vital for successful implementation of SPC to improve process capability, with the hope that the study findings and applications used in the study (e.g. statistical techniques and experimental designs) could be generalised across the winder manufacturing environment.

1.4.2 Practical Value

Hung and Sung (2011) found that in many instances, the staff lacked experience in using statistical tools and this acts as a barrier for launching quality improvement initiatives in contract manufacturing companies. There is a need to find out how to maintain good quality and to increase profit via implementing SPC and how this fulfils intrinsic motivational needs of staff. Moreover, the research contains recommendations on SPC implementation, which could benefit those who practise SPC in a similar manufacturing environment. The improvement of product quality in PCM could potentially reduce the price of products by reducing the cost of manufacturing.

1.4.3 Researcher's Background

The third driver of the research is the researcher's background. The researcher is an analytical chemist (Bachelor of Chemistry from the University of Auckland) with good academic training on quality control, thanks to Massey University. The researcher has a great deal of appetite for analytical work in general and the application of statistics for workplace improvement in particular.

1.5 RESEARCH AIM AND OBJECTIVES

The aim of the research is to study the application of SPC methods in the PCM industry and to identify the factors that influence SPC implementation. The study contributes to quality management body of knowledge by being able to examine the attitudes of operators in the case study company and which affects in developing quality strategies and cultures conducive for continuous improvement.

The general objective of the research is to provide useful recommendations for the company used in the case study with the hope that these recommendations would be useful to other PCM environments.

The specific objectives of the study are:

1) To identify a suitable SPC programme for a PCM company.
2) To identify enablers for implementing SPC in PCM.
3) To assess the suitability of SPC tools to handle a critical to quality variation problem in a PCM case study company.
4) To identify the enablers of quality performance in a PCM environment and explain how these enablers cause quality performance.

1.6 RESEARCH QUESTIONS

The following research questions will be discussed in the following chapters:

- What constitutes an acceptable SPC programme for a typical PCM company? (RQ1)
- Given the SPC programme, what are the critical enablers for implementing SPC in a PCM company? (RQ2)
- To what extent do SPC tools help in solving critical-to-quality variation problems in a PCM process? (RQ3)
- What are the enablers of quality performance and how do they cause quality performance (RQ4)?

1.7 METHODS OVERVIEW

This study can be classified as a positivistic/quantitative study based on process data obtained from a manufacturing process as well as data obtained through a survey questionnaire to elicit both quantitative data and qualitative data. A general strategy recommended by Simon, Sohal, and Brown (1996) is to use both qualitative and quantitative techniques to achieve more enriched, pragmatic outcomes, as use of both techniques means one technique compensates for the limitations of the other.

RQ1 and RQ 2 were answered through a comprehensive literature review (Chapter 2) followed by fieldwork. For RQ1, the fieldwork involved the work in

answering RQ3 (see below). For RQ2, the fieldwork involved the work in answering RQ4 (see below).

RQ3 was answered by receiving feedback on the quantitative methods used in the case study aimed at implementing SPC tools in a critical to a quality problem (Chapter 4).

RQ4 was answered using data collected from the survey questionnaire designed to operationalise the *hard factors* and *soft factors* for success in total quality management (TQM) (Hietschold, Reinhardt, & Gurtner, 2014; Lewis, Pun, & Lalla, 2006; Powell, 1995), given the quality improvement environment (PCM company understudy). Because the researcher treats SPC as a standalone company-wide quality improvement approach, it was difficult to isolate SPC from TQM at abstract level (more explanation given elsewhere). To answer RQ4, data were collected by the researcher from 76 respondents in the case study company to understand organisational culture (more precisely, quality improvement climate), which for the most part, dictates TQM/SPC implementation success (Chapter 5).

1.8 STRUCTURE OF THE THESIS

The remaining parts of this thesis is structured as follows:

Chapter 2, the “literature review”, begins by introducing SPC, statistical thinking, and different types of variances. These concepts form the basis of the next concept reviewed in Chapter 2, which is continuous improvement. Thereafter enablers for quality performance are reviewed, followed by SPC implementation. Finally, Chapter 2 reviews quality improvement in the PCM industry to identify the research gaps that justify the research questions raised earlier.

Chapter 3, “methodology”, begins with an overview of research paradigms (worldviews) available to conduct social research along with the justification of the paradigm chosen by the researcher. This is followed by introduction the

context: the case study PCM company and the particular product category chosen for SPC implementation trials, which is hard-shell capsules, its manufacturing processes, and quality (non-conformance) issues associated with the product. Thereafter, Chapter 3 describes how the researcher went about in conducting an SPC implementation trial to collect quantitative and qualitative data, which are required to answer RQ1 and RQ3. Thereafter, four hypotheses are posited based on extant literature and two conceptual models (in actual fact, two testable theoretical models) are presented to correspond to the hypotheses. Thereafter Chapter 3 describes how a quantitative survey questionnaire containing Likert statements was developed and administered to collect data to test the conceptual models statistically; human ethics considerations are also covered. Finally, Chapter 3 concludes with a description of how the survey was administered and data were analysed to test the conceptual models and thereby answer RQ2 and RQ4.

Chapter 4 covers results and discussion of the case study: an SPC implementation mini journey. Weight variation was selected as the most frequent problem in hard shell capsule manufacturing process. A brief introduction on hard shell capsule manufacturing process is given, followed by sources of variability, identification of activity performed within the Quality Improvement team formed by recruiting critical members from the Production team and Quality Assurance team. Data generated by the application of SPC tools including the Ishikawa diagram, $\overline{X}$ - S control chart, process capability analysis conducted via Minitab software (the six-pack report) are presented; the purpose of this was to engage members of the quality improvement team to observe how they react to the new things that they learned; in some ways the approach used by the researcher resembled the “ethnography” approach used in social research (Bryman, 2012). This chapter then marshals evidence provided by the quantitative data analysis (process stability and capability analysis via Minitab) and qualitative data analysis (participants’ verbal and non-verbal responses) in order to answer RQ1 and RQ3 related to the first and the third research objectives.

Chapter 5 discusses data analysis results of quantitative survey data (collected from the 76 respondents) that go as measurement items of the constructs

contained in the theoretical model. Consequently, data analysis results for the most part covers the results of structural equation modelling (with justification, partial least squares structural equation modelling was used and SmartPLS was chosen as the structural equation modelling software), which are required to confirm or refute the two hypotheses on SPC implementation. The test results also demonstrate the relationship among the key success factors. The discussion includes in Chapter 5 answers RQ2 and RQ4, allowing the researcher to achieve the second and fourth research objectives.

Chapter 6 concludes the study, reflecting upon the findings that enabled the researcher to archive the research objectives. Consequently, a summary of key achievements of this study, limitations and direction for future work are mentioned in this chapter.

1.9 DELIMITATIONS AND LIMITATIONS

A production process involves many upstream and downstream activities (i.e. supply chain activities) not just the value-adding activities that takes place in the production floor of a PCM production plant. Besides, many support activities are needed in manufacturing (e.g. invoicing, complaints handling, personnel management, safety training, payroll etc.) and support staff also deal with the external customers directly. The delimitation (boundary) of this study is activities that takes place at floor-level (supervision of workers and on the job training included) in a PCM plant. The subject area covered in this study relates to those aspects of pharmaceutical and Nutraceutical - nutritional-pharmaceuticals manufacture that are intimately associated with production (i.e., core value-adding activities within the plant).

Results obtained from a single case study company may not represent the production and cultural environment of other companies that produce the same product. Even the size and scale of operation may influence SPC implementation and TQM success. Hence, the conclusions should be interpreted with caution.

Chapter 2 LITERATURE REVIEW

2.1 STATISTICAL PROCESS CONTROL

SPC is a technique that uses statistical methods to monitor data from a manufacturing process (Hoerl & Snee, 2012). This data can be attribute data (for example: no of defective tablets in a sample of 200, sampled every two hours) or variable data (for example: time to dissolve a tablet in a subgroup of five tablets sampled every hour). SPC is a powerful technique to control, manage, analyse and continuously improve the performance of a process by reducing process variability, such as operator error, errors in measurements and use of improper raw material, etc. (Rahman et al., 2015). SPC is used to check (and take corrective action when necessary) the predictability/stability (phase 1) and capability of a manufacturing process (phase 2).

1) The first phase is to monitor whether the process is under statistical control by plotting data in control charts; control chart rules are used to check whether the process is in statistical control. If there is any indication(s) of a potential assignable cause being present (for example: one point being outside the control limits), this needs to be investigated, and the assignable cause eliminated as soon as practicable (Wheeler & Chambers, 1992). This is to prevent unnecessary out-of-spec items from being produced. To this end, a combination of SPC tools with other quality tools to find the cause of uncontrolled processes and make adjustment.

2) The second phase is to determine process capability, which is the ability of a process meeting the requirement by calculating capability indices of the process.

   Process Capability Analysis is a powerful tool that used to quantify the capability of the studied process to produce product meets the design process specifications. This tool can be used to predict what portion of the

overall population of product produced will fall outside of the customer's agreed process specification limits – and thus result in a defect.

Process Capability can be described as a comparison of process performance against its process specifications using various capability indices. Process specifications are the pre-defined specifications associated with the product, which generally defined by the Lower Specification Limit (LSL) and the Upper Specification Limit (USL) (Figure 2-1).

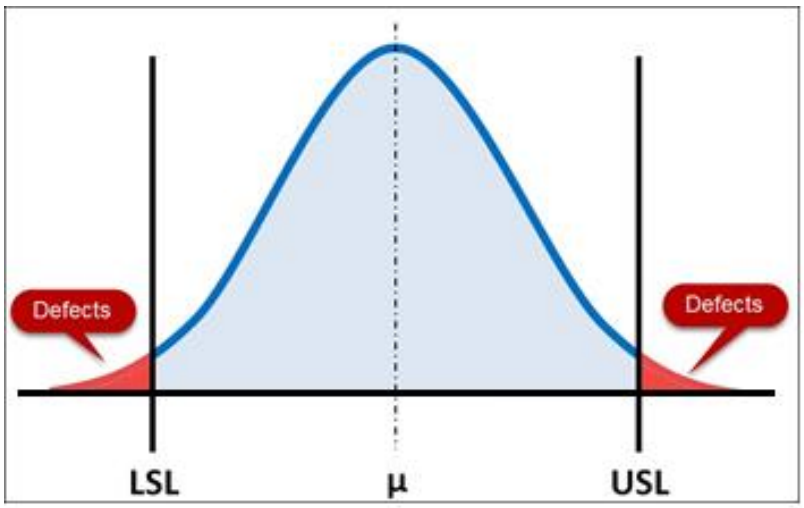


Figure 2-1 Process capability (CQE Academy, n.d.)

To have a better understanding of the SPC, first, we need to understand a term that W. E. Deming often used – "Statistical thinking". It is to recognise all processes are subject to variability and that improvement comes about through understanding and reducing variability.

2.2 STATISTICAL THINKING IS NOT A NEW PROGRAM

Statistical thinking was promoted by Dr. Deming using Red Bead and Funnel experiments (Stamatis, 2003). The concept was then being introduced as a process analysis tool that has strong links to many business strategies. Based on the principles listed below, statistical thinking provides a methodology for effective continuous improvement (Evans & Lindsay, 2005).

1) All work occurs in a system of interconnected processes
2) Variation exists in all processes
3) Understanding and reducing variation are keys to success.

Makrymichalos et al. (2005) illustrated six possible reasons for lack of statistical thinking in business (Figure 2-2). This requires managers to change the mindset and attitude of thinking toward work activities. They should also understand that statistical thinking is much more than a set of statistical tools and techniques. It is also essential for the managers of the 21st century to be able to distinguish the common and special cause variation and thereby establishing a more excellent knowledge of the process.

Figure 2-2 Reasons for lack of Statistical Thinking mindset (Makrymichalos et al., 2005)

2.3 WHAT IS VARIANCE?

Variance provides an idea of how data is spread out about the centre of a distribution. Take bottling as an example. Continuously putting in more capsule than needed into a bottle, there will be incurring an excessive use of material to complete customer's orders; the direct material cost will be increased. On the other hand, if the quantity of capsule inside of a bottle is less than the specified, profit will be increased with a lower cost of manufacturing. However, in the meantime, it will bring customer dissatisfaction. Therefore, understanding and reducing variation is critical to improving quality.

There are two types of variance, and both need different approaches to solve and to minimise the causes (Hoerl & Snee, 2012). The use of SPC can help us understand the type of variation present and which type of action would be recommended to deal with that variation (Rahman et al., 2015).

2.3.1 Common Cause of Variance

Common cause of variance is known as noise and it is an inherent part of a process that is active within the system (Summers, 2010). This variation appears as random dots in a control chart sitting within the control limits. To reduce the level of this type of variance, a fundamental change of the system is required.

2.3.2 Special Cause of Variance

Special cause variance is new unobserved variation in the system (i.e. variation that did not exist previously). It is not predictable (as it is not inherent) and may cause a significant impact on the process (Summers, 2010). This variance can be identified in the control chart based on "control chart rules". Special treatment and immediate action are required to prevent it from recurring.

Any process can contain many sources of both common causes and special causes of variations. If both the process averages and variances in the process are constant over time, the process is in statistical control. Figure 2-3 shows a

manufacturing process is the transformation of multiple variables to final output items. The reduction of variation leads to improvement in quality and productivity.

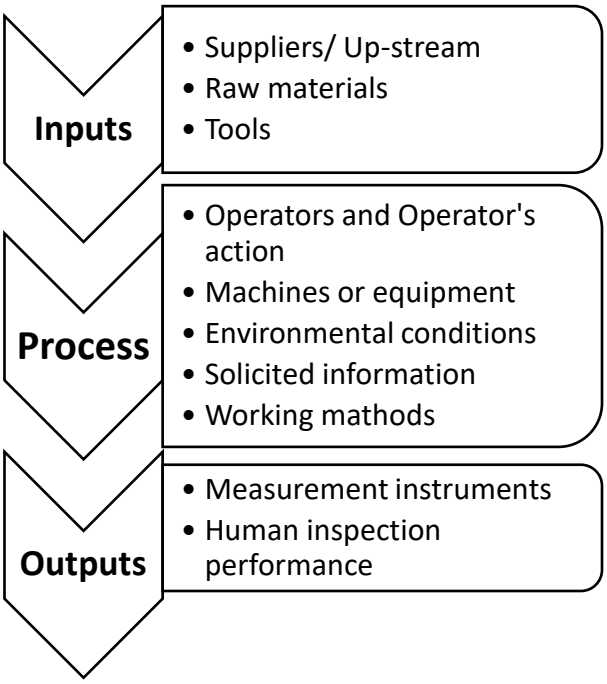


Figure 2-3 Sources of variation in a manufacturing process

2.4 NON-STOP IMPROVEMENT PROCESS

Define the root causes of the variation using different tools and brainstorming sessions is essential when a variation is detected. The PDSA (Plan-Do-Study-Act) improvement cycle (Figure 2-4) created by Edward Deming is a schedule for quality used for systematic continuous improvement activities. This four-stage problem-solving model is covering the problematic causes of variations, improves the quality of the product and creates consistency (Beckford, 2010).

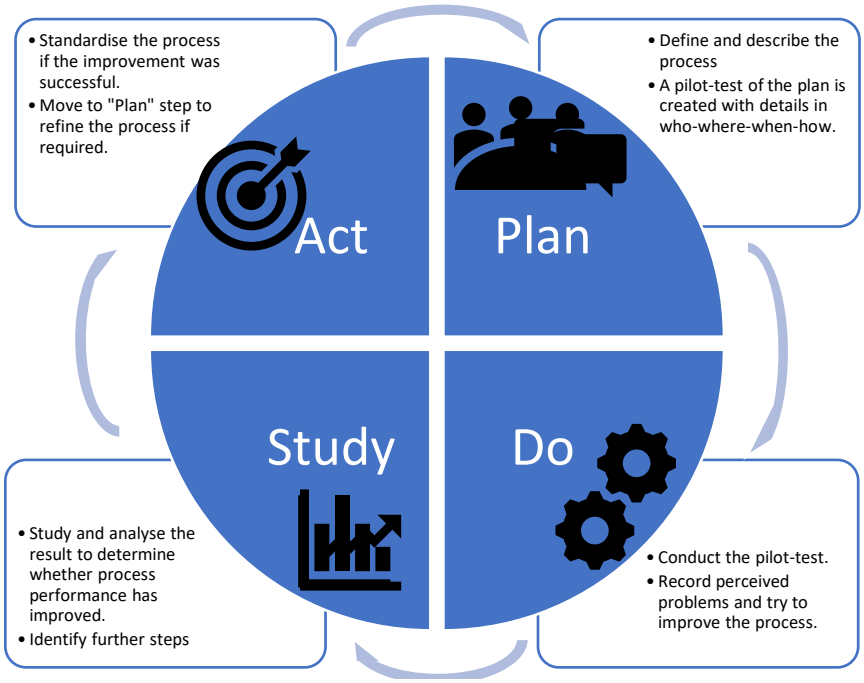


Figure 2-4 PDSA cycle (Evans & Lindsay, 2005)

Every process starts with a quality plan and identifies any deficiencies. It then performs correction actions on the variations from the actual performance that differ from requirements. Once the cycle is completed, it starts again from the plan and 'do it all over again'. These continuous cycles will provide non-stop improvement, which can make the process more effective. Increasingly, organisations are recognising the importance of continuous improvement as a part of effective quality management. Meanwhile, this is an essential concept during SPC implementation.

2.5 SPC IMPLEMENTATION

Variation exists in all processes and is unavoidable. With this in mind, it is important to understand that no two products can be manufactured to be exactly the same. The amount of this basic variability will depend on various characteristics of the production process. The hard and soft factors of SPC implementation can be used to identify the critical factors of implementing SPC in the pharmaceutical industry during a literature survey and further utilised in the case study.

Despite the successful application of SPC tools have had on the practice of management in Japanese companies, other organisations are not successful and are still struggling in implementing SPC. The result of this study shows that without these soft factors, companies are unable to implement SPC successfully.

It is interesting to note that a lack of understanding of the potential benefits of SPC is one of the reasons for the failure to introduce SPC (Antony, Balbontin, & Taner, 2000). The benefits and results of successful SPC implementations have been reported in various publications (Table 2-1).

Table 2-1 Results of Successful SPC Implementation

Author and Year **Factors**	Gordon, Philpot, Bounds, and Long (1994)	Rungtusanatham, Anderson, and Dooley (1997)	Xie and Goh (1999)	Deleryd, Deltin, and Klefsjö (1999)	Antony et al. (2000)	Grigg and Walls (2007)
Improve quality	x	x	x			
Increased worker participation	x					
Reduction of costs		x			x	x
Few problem				x		
Continuous improvement			x			x
Improve capability				x	x	
Defection rate reduced			x	x		
Improve delivery				x		
Understanding process performance					x	
Distinguish special causes from common causes of variation, and remove of variations					x	
reduction on time spent firefighting quality problems					x	
Better communication					x	
makes an organisation statistically oriented					x	
lays the groundwork for process improvement, allowing the process to improve the quality of the finished product, lower cost and increase productivity					x	
Improve competitiveness						x
Improve customer and producer confidence in product						x
Improve process visibility and understanding						x
Enhance legal compliance						x

In this literature review, the researcher investigates in what has been classified as soft and the hard aspects of SPC implementation. “Soft” aspects are mainly related to intangible factors that focus more on human and behavioural aspects and quality management. On the other hand, “hard” aspects are mainly concerned with tangible factors such as SPC tools.

2.5.1 Enablers (Soft Factors)

Since Deming elaborated on the SPC principles and introduced it to the Japanese manufacturing industry, his 14 management methods published in *Out of Crisis* (1986) are initial enablers for quality management and implementation of SPC. From then, several other experts identified specific management factors or activities associated with the successful implementation of SPC, which provide valuable soft factors to build upon these 14 points (Figure 2-5).

The Deming Management Method[a]

Point 1.	Create constancy of purpose toward improvement of product and service with the aim to become competitive and to stay in business, and to provide jobs.
Point 2.	Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership of change.
Point 3.	Cease dependance on mass inspection to improve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
Point 4.	End the practice of awarding business on the basis of price tag alone. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
Point 5.	Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
Point 6.	Institute training on the job.
Point 7.	Institute leadership. The aim of supervision should be to help people and machines and gadgets to do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers.
Point 8.	Drive out fear, so that everyone may work effectively for the company.
Point 9.	Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and use that may be encountered with the product or service.
Point 10.	Eliminate slogans, exhortations, and targets for the workforce asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the workforce.
Point 11.	a. Eliminate work standards (quotas) on the factory floor. Substitute leadership. b. Eliminate management by objective. Eliminate management by numbers, numeric goals. Substitute leadership.
Point 12.	a. Remove barriers that rob the hourly worker of his [or her] right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality. b. Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means, inter alia, abolishment of the annual or merit rating and of management by objective.
Point 13.	Institute a vigorous program of education and self-improvement.
Point 14.	Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job.

Figure 2-5 Deming's 14 management methods (Deming, 1986)

Table 2-2 Enablers for SPC Implementation

categories	Authors / Enablers	Gordon et al. (1994)	Rungtusanatham et al. (1997)	Xie and Goh (1999)	Deleryd et al. (1999)	Antony et al. (2000)	Grigg and Walls (2007)	Pun and Jaggernath-Furlonge (2009)	**Factors Frequency**
Internal enablers	Management action includes commitment and support	x	x	x	x	x	x	x	7
	Training	x	x	x	x	x	x	x	7
	SPC tools usage		x	x		x		x	4
	Process knowledge; process prioritisation and definition	x	x	x		x	x		5
	Teamwork	x		x		x		x	4
	Technical support for SPC implementation and practice		x	x		x	x		4
	Awareness and willing to change			x	x	x			3
	The involvement of workers in decision making process	x	x					x	3
	Critical measurement and measurement technology		x			x	x		3
	Operator responsibility for process control via control charts	x	x			x			3
	Quality improvement team support of SPC practice		x	x			x		3
	Use of computer and software package		x		x	x			3
	Continuous improvement			x			x		2
	Sampling strategy		x		x				2
	Pilot projects				x	x			2
	Communication				x				1
	Management aspects of SPC			x					1
	Verification of control charting assumptions		x						1
	Absence of final inspection as a quality control strategy		x						1
	Audit		x						1
	Corrective action			x					1
	Process capability study				x				1
	Cross-functional team				x				1
	Job security	x							1
	Selection of appropriate quality characteristics					x			2
	Identify critical quality								1
	Innovation							x	1
	Customer satisfaction							x	1
	Facility size						x		1
	Self-assessment against an excellence model						x		1
External enablers	Competitive pressure experienced by the supplier; supplier management						x	x	2
	Available advice and information						x		1
	External bench marking, network participation						x		1
	Network participation						x		1
	Customer support						x		1
	Maintain a competitive edge							x	1
	Attract customer							x	1
	Promote exports							x	1
	Safety customer against pressure from environment							x	1

Enablers for SPC implementation were summarised in Table 2-2. Gordon et al. (1994) were among the first researchers to study the SPC implementation issues. Three years later, Rungtusanatham et al. (1997) developed a measurement instrument that operationalised the 14 dimensions underlying the SPC implementation. The results of their study provided some evidence and some insights into how the SPC implementation/ practice construct might be measured in the organisational setting. Xie and Goh (1999) identified three main aspects, namely, management aspects, human aspects and operational aspects that are very crucial for the successful implementation of SPC. In the same year, Deleryd et al. (1999) identified important success factors after conducting process capability implementation at nine Swedish organisations. Antony et al. (2000) identified and discussed ten key ingredients for the successful implementation of SPC in both manufacturing and service organisations. Grigg and Walls, in 2007, described and categorised the success of SPC implementation will depend upon both external and internal to organisations. The internal factors that are essential to SPC success which defined as drivers an organisation needs to implement to achieve quality. The external factors, on the other hand, are not limited to the drivers of quality from external customers; these are the factors that organisations could obtain from various outside sources. In 2009, Pun and Jaggernath-Furlonge summarised a list of critical internal and external factors that are useful for SPC implementation as well as the organisation's future development.

Based on extant literature, the researcher has summarised that the SPC being introduced into organisations is attributed by two categories of motivational enablers:

- Internal enablers: to improve manufacturing and process quality
- External enablers: to satisfy customer demands.

The most important enablers are

1) Management action, including commitment and support. Implementing SPC requires total commitment from upper management. The

participation and dedication showed by upper management are essential to the success of process control.

2) Training. Successful employee involvement and empowerment effort require providing process knowledge, quality improvement and problem-solving skills, and quality awareness. Upper managers also need to be involved with the training in order to make decisions when these techniques can be employed to improve quality.
3) SPC tools usage. Upper management and operators need to understand SPC concepts and techniques to solve a problem effectively.
4) Process knowledge. Understanding the studied process is key to utilise SPC to reduce variation in the process. Hence, broad-based involvement is important
5) Teamwork. The team-oriented factor has values of being innovative, creative and sharing information freely so that employees can make better decisions and achieve continuous improvement. Effective teamwork requires employee involvement and communication.
6) Technical support for SPC implementation and practice. Companies with an SPC facilitator are less likely to experience difficulties with the introduction and application of SPC. The facilitator should be able to provide guidance and advice on all technical and statistical aspects of SPC.
7) Awareness and willingness to change. Willing to change the structure of the organisation and implement the changes which continuously improve the process.
8) The involvement of workers in decision-making process. The majority of the manufacturing business moves to automated processes. Notwithstanding, the design, maintenance, and operation of the process strongly rely on the employee. Management motivates staff, provides tools to continuously improve their job and states expectations about employees recognizing and solving problems and empower them to do so. With a shared vision and a set of agreed continuous improvement objectives for the company, empowered employees know which direction to work on and involve in continuous improvement. The lower level of an organisational

hierarchy has the authority to make decisions and contribute to quality improvement, which is attributable to efficiency.

2.5.2 Strategies and Techniques (Hard Factors)

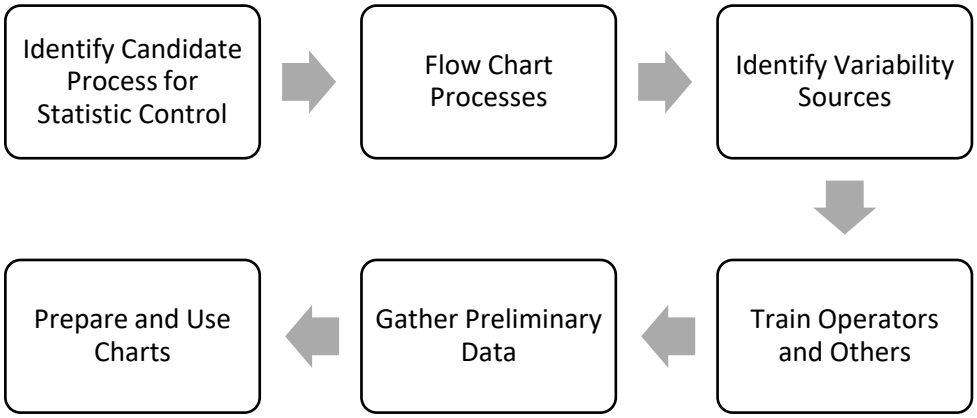


Figure 2-6 A Six-step process for SPC implement (Berk & Berk, 2000)

The Six-step implementing SPC process is illustrated in Figure 2-6. Instead of implementing SPC as a reaction to evidence of decreasing product quality, this powerful technique can achieve continuous improvement in the selective process.

Step 1: Identify candidate process for statistical control

Identify and focus on the key processes for implementing SPC, for example, process with a high reject rate. Select a candidate problem by using Pareto charts, which can be used to display potential categories of problems graphically so they can be properly prioritised. The involvement of the quality improvement team is essential, staff from relevant departments brainstorming to find effective outcomes.

Step 2: Flow chart processes

A detailed flow chart of the process is very critical, as it breaks the process down into sub-processes, which helps everyone in the quality improvement team to understand the activities and outputs of the process.

Step 3: Identify Variability sources

Analysis of the selected process to identify variability sources using statistical techniques such as histogram and cause and effective diagram. Histogram identifies inputs of variation by displaying a frequency distribution of the occurrence of the various measurements. The cause and effective diagram known as fishbone chart which organises and displays the relationships between different causes for the process. The major categories of causes are put on significant branches connecting to the backbone, and various sub-causes are attached to the branches. This is a handy technique that helps to organise the brainstorming process.

Step 4: Training management and operators

As one of the most important purposes of the SPC is monitoring of the process and identifying when the process is out of control. Operators and management must understand the principle and concepts of SPC, implementation methodology, as well as problem-solving techniques and SPC tools.

Step 5: Gather preliminary data

A quality characteristic of the process can be measured from several dimensions. There are several tools for data gathering and initial charting, such as check sheet. It assists in gathering accurate and pertinent data and allow the data to be easily read and used.

Step 6: Prepare and use charts

Collected data then will be analysed using appropriate control charts and other statistical techniques such as probability plot. Control charts represent the variability graphically in a process over time. When used to monitor the process, control charts can uncover inconsistencies and unnatural fluctuations. The probability plot is useful in analysing data for normality, and it is particularly useful for determining how capable a process is when the data is not normally distributed.

Out of the control process will be investigated to determine the assignable causes, then corrective actions need to be taken to improve the process. The greater understanding of quality improvement leads to the optimal implementation of SPC for the reduction of variability in the process. Implement SPC provides techniques identifying, characterising, quantifying and controlling variations. Utilise this effective method together with continues process improvement strategy to increase process efficiency and quality and productivity of the product further increase competitiveness in the market.

2.5.3 Relationships Between Soft Factors and Hard Factors in Explaining Results

Empirical studies on the relationships between soft factors and hard factors depend on the particular theorisation that one is looking at. For example, in their seminal work, Anderson, Rungtusanatham, and Schroeder (1994) in theorising the Deming Management Method (DMM), posited that outcomes of the DMM are caused by four factors: Visionary Leadership (driver); Internal and External Cooperation; Learning; and Process Management. Closer examination of these factors reveals that only Process Management remains a hard factor (the remaining three factors are soft factors as shown in Figure 2-7).

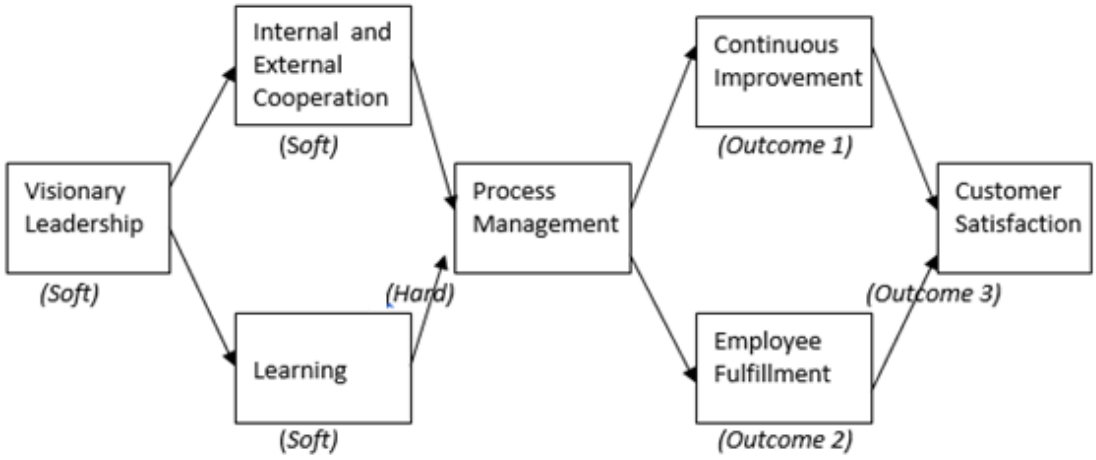


Figure 2-7 The factors that underlie the DMM and their relationships (Adapted from Anderson et al., 1994)

Similar reasoning can be given other organisation-wise quality improvement theories. For example, European Foundation for Quality Management (EFQM) Excellence Model, which is made up of nine elements grouped under five enabler criteria and four result criteria. Among the five enabler criteria, Leadership and People Management are soft factors, while Partnerships and Resources and Processes are hard factors. Policy and Strategy can be considered as both soft and hard factors (Figure 2-8) (Bou-Llusar, Escrig-Tena, Roca-Puig, & Beltrán-Martín, 2009).

Figure 2-8 The EFTQ Excellence Model (Bou-Llusar et al., 2009)

Baldrige Framework is another example. Among the six Baldrige criteria, Leadership, Customer and Market Focus, Strategic Planning, and Human Resource Focus are soft factors, while Measurement, Analysis, and Knowledge Management and Process Management are hard factors (Figure 2-9) (Jayamaha, Grigg, & Mann, 2009).

Figure 2-9 Baldrige Criteria for Performance Excellence framework (Jayamaha et al., 2009)

One common point from these models is the soft factors drive the hard factors. In a sense, without the soft factors, it is difficult to make hard factors work in effecting quality improvement. For example, without developing an effective problem-solving culture, hard factors such as measurement, analysis and knowledge management have limited success in quality improvement.

Soft factors are hard to develop and the way these soft factors are bundled is hard to imitate by a competitor. Resourced based view of competitive advantage argues that it is these soft factors and not the hard factors that provide an organisation the competitive advantage (Powell, 1995). Powell first suggested this, and later, lots of researchers jumped on the bandwagon.

2.6 PHARMACEUTICAL INDUSTRY

The pharmaceutical industry follows quality by testing, which is relying on finish product testing and inspection to test quality (Korakianiti & Rekkas, 2010). There

is still an established four-step sequential process of producing medicinal products: manufacturing, quarantine, testing and release to the market. This practice involves raw and in-process material testing, manufacturing following an already approved fixed process, and final testing of the finished product to check if it meets its predefined characteristics. The inspection practice is an expensive quality control technique and unreliable practice. It does not guarantee that a defective product will not pass the test, and defective products are identified too late in the process. This is one of the reasons for several recalls from the market (Deming, 1986) (Antony & Taner, 2003). When a failure is observed, defective products have already been produced, and the cost of poor quality in terms of scrap and rework is increased.

Goh (2002) has noted that in the pharmaceutical industry, inspection and testing merely detect defective product units and prevent them from going downstream to the next process or customer. This approach does not facilitate quality improvement. Instead, it is much better to focus on the upstream process, which produced the product in the first place. SPC as an alternative technique, emphasises early detection and prevention of problems that can be applied to investigate variability in pharmaceutical production. The purposes of these techniques are (Ryan, 2011):

- Identify abnormal variations in the process.
- Determine changes in the values of process parameters
- Identify factors that are influencing process characteristics.

The safety of the patient is the most crucial consideration that drives the push for better quality. The general rule for product suitability is that the dosage form should meet the following criteria:

- QUALITY (microbiological status, product form)
- QUANTITY (weight, potency)
- PURITY (consistency)
- CONTAMINANT-FREE.

In a high-volume production environment, it is essential to ensure that crucial process variables and parameters are within the specification limits. Adjustments and changes to the process are usually required to ensure all applicable quality requirements. In most cases, problems are not caused by an isolated factor. They are the result of interactions between several factors, including quality ingredients, parameter settings and other processing conditions.

According to the AMR report, “Pharmaceutical Quality: Build it into the Process” (Smith & Martin, 2004). The industry average for both rework and discarded product is 50%, on hold product inventories are at the 40 - 60 days level on average, plant utilisation levels run at 40 - 50%, average cycle times are in the 30 - 90 days range and laboratory bottlenecks can add as much as 75% to the cycle time. The bottom line of the report is that “reducing cost and cycle times require pharmaceutical manufacturers to take variability out of core production processes with an integrated approach to Enterprise Quality Management.” An integrated approach across operations is key to achieving the desired process performance. Unfortunately, however, currently there is a reduced flow of knowledge between the different pharma operations, i.e., clinical, commercial, quality and regulatory. It has been reported that the pharmaceutical industry suffers from the so-called data rich/ information poor (DRIP) syndrome (Smith & Martin, 2004). It is document-centric and fails to integrate or align business and information processes of creating the necessary framework to transfer business, science and compliance data across organisational silos. Moreover, while the amount of information that pharmaceutical companies generate and collect during drug development doubles every 5 years, only 10% of its information is ever leveraged to improve overall competitiveness and compliance.

All the shortcomings of Pharma manufacturing discussed above have been acknowledged by FDA (Food and Drug Administration) Innovation in its cGMP (Current Good Manufacturing Practice) for the 21st century initiative report with a clear call for action. According to this report, the processes are static, the functionality of the material characteristics in relation to the process is not well understood, out-of-specification values occur frequently, there is variability in the measurement systems, a difficulty in differentiating between common and special

causes variability is observed, and the information needed for continuous improvement is segregated in different departments (Smith & Martin, 2004).

2.7 KOWLEDGE GAPS AND JUSTIFICATION OF RESEARCH QUESTIONS

The potential of SPC has been underestimated in most cases, especially in the Pharmaceutical industry that share some common ground with SPC (e.g. measurement and analysis). It is not just the SPC tools (e.g. control charts) that make SPC successful as they are just tools being used in the practice of SPC. There are some critical factors or enablers of successful SPC implementation.

This chapter examined the literature on enablers for SPC implementation (see Section 2.5 for details). Firstly, the literature review revealed that, understanding the potential benefits of SPC is one requirement for successful SPC implementation. Secondly, the literature review revealed that hard and soft factors of SPC implementation need to be isolated to identify the critical factors of SPC implementation. Thirdly, the literature review found that SPC being introduced into organisations is attributed to internal enablers and external enablers. Last but not least, the literature review enabled the researcher to summarise the 10 most important enablers.

Berk & Berk (2000) provided a six-step process for SPC implementation (see Section 2.5.2) where hard factors come into play more than soft factors; this approach seem to fit well continuous process improvement strategy (see Section 2.4) to increase efficiency of the implementation process. However, what constitutes an acceptable SPC programme for a typical PCM company remains to be seen (not covered in the literature). This justifies RQ1. Related this is within an acceptable SPC programme, the extent to which SPC tools help a PCM in solving critical to quality variation problems. This justifies RQ3.

- What constitutes an acceptable SPC programme for a typical PCM company? (RQ1)
- To what extent do SPC tools help in solving critical-to-quality variation problems in a PCM process? (RQ3)

Anderson et al. (1994) posited that outcomes of the DMM are caused by both soft and hard factors. Similar to EFQM Excellence Model (Bou-Llusar et al., 2009) and Baldrige Framework (Jayamaha et al., 2009), without the soft factors, it is difficult to make hard factors work in effecting quality improvement. While academia appreciate that soft factors are more important than hard factors, no one has attempted to estimate how much more important soft factors are than hard factors (a ratio or proportion). Another gap in the literature is lack of clarity in explaining how soft factors do and hard factors work in tandem to improve quality performance. These gaps were filled by the research through the remaining two research questions (RQ2 and RQ4).

- Given the SPC programme, what are the critical enablers for implementing SPC in a PCM company? (RQ2)
- What are the enablers of quality performance and how do they cause quality performance (RQ4)?

2.8 SUMMARY

This chapter was dedicated to reviewing the literature on SPC and interrelated concepts – statistical thinking, variation, and non-stop (continuous) improvement process. Through the review of the literature, the researcher reviewed the fundamentals of process variation (e.g. two distinguishable types of variation) as these form the basis of statistical process control. If both the process averages and variances in the process are constant over time, the process is in statistical control. SPC is used to check the predictability/stability and capability of the process.

The researcher also reviewed the literature surrounding SPC implementation within and outside PCM. The review involved understanding soft factors as well as hard factors of SPC/TQM implementation. These concepts were used in later chapters to answer research questions and thereby achieve the research objectives. The next chapter covers the methodology adopted by the researcher to answer the research questions.

Chapter 3 METHODOLOGY

3.1 INTRODUCTION

This chapter covers the methodology used to answer the research questions. Section 3.2 examines three dominant research paradigms (worldviews) that a researcher can recourse to, in researching quality management and related disciplines that involve interactions with people. The paradigms positivism, constructivism and pragmatism are introduced, and the researcher's justification of her paradigm (positivism) is provided.

3.2 RESEARCH PARADIGMS

The research paradigms are a critical component in a research design framework because a social scientist's worldview on a particular phenomenon of interest can be different to that of a hard scientist. Specifying the paradigm is the logical first step in one's research design because it is what guides one's research (Creswell, 2014). Put simply, a paradigm spells out one's assumptions about research, including one's assumptions on reality and one's assumptions on knowledge (Onwuegbuzie & Leech, 2005; Mackenzie & Knipe, 2006; Easterby-Smith, Thorpe, & Jackson, 2015). How one views what is real, what they know and how they know it, along with the theoretical perspective(s) one has about the topic under study, the literature that exists on the subject, and one's own value system work together to help a researcher in selecting the most appropriate paradigm. Ontology, epistemology and methodology are the three key constituents of a research paradigm (Onwuegbuzie & Leech, 2005; Easterby-Smith et al., 2015).

Ontology is essential to a paradigm, because it helps to provide an understanding of the foundational concepts which constitute themes that researchers analyse to make sense of the meaning embedded in research data (Scott & Usher, 2004). It is a philosophical study that helps the researcher to conceptualise the form and nature of reality and what the researcher believes can be known about that reality.

It concerns the very nature or essence of the social phenomenon researchers are investigating (Scotland, 2012). Ontology enables researchers to examine the underlying belief system and philosophical assumptions and concepts. Typical ontology questions are:

- “Is there reality out there in the social world, or is it a construction created by one’s mind?” (Kivumja & Kuyini, 2017, p.27)
- “What is the nature of reality?” (Kivumja & Kuyini, 2017, p.27)
- “Is the reality of an objective nature, or the result of individual cognition?” (Kivumja & Kuyini, 2017, p.27)
- “What is the nature of the situation being studied?” (Kivumja & Kuyini, 2017, p.27)

Epistemology is the study of the nature of knowledge and justification (Schwandt, 1997). It focuses on the nature of human knowledge and comprehension that the researcher can possibly acquire to be able to extend, broaden and deepen understanding in the field of research. Epistemology questions are important because they help the researcher to position themselves in the research context so that they can discover what else is new, given what is known. Typical epistemology questions are:

- “Is knowledge something which can be acquired on the one hand, or is it something which has to be personally experienced?” (Kivumja & Kuyini, 2017, p.27)
- “What is the nature of knowledge and the relationship between the knower and the would-be known?” (Kivumja & Kuyini, 2017, p.27)
- “What is the relationship between me, as the inquirer, and what is known?”
- “How do we know what we know?” (Kivumja & Kuyini, 2017, p.27)

The last question can help the researcher to understand the epistemological element of the paradigm. Further to ask factual questions, for example,

- “How do we know the truth?” (Kivumja & Kuyini, 2017, p.27)
- “What counts as knowledge?” (Kivumja & Kuyini, 2017, p.27)

From these epistemology questions, researchers can learn from intuitive knowledge, authoritative knowledge, logical knowledge, and empirical knowledge (Slavin, 1984).

The methodology which are research design, methods, approaches and procedures used in an investigation (Keeves, 1997). The methodology articulates the logic and flow of the systematic processes followed in conducting a research project, in gaining knowledge about a research problem (Kivumja & Kuyini, 2017). It includes assumptions made, limitations encountered, and how they were mitigated or minimised. It focuses on how we come to know the world or gain knowledge about a part of it (Moreno, 1947). The typical methodological question is:

> "How shall the researcher go about obtaining the desired data, knowledge and understandings that will enable him or her to answer the research question and thus make a contribution to knowledge?" (Kivumja & Kuyini, 2017, p.28)

3.2.1 Positivism and Post-positivism

Ontology refers to what a researcher considers as reality (Creswell, 2014). The board question is that reality is real (meaning it is not shaped by the observer) or idealistic, meaning it is shaped by the observer, who becomes part of the phenomenon of interest (Creswell, 2014; Mackenzie & Knipe, 2006). The positivistic ontology (also known as the naïve realism) holds that the reality is "singular and objective", that it is governed by "natural laws and mechanisms" and those laws and mechanisms can be precisely measured and controlled, that they can be understood through cause-effect propositions (Creswell, 2014; Crook & Garratt, 2011; Easterby-Smith et al., 2015; Guba & Lincoln 1994). This paradigm supported the program of the discovery of obtainable facts. The role of the researcher, based on positivistic epistemology, is to record precise measurements that is observed by testing cause and effect hypothesis (cause-effect). Though visible throughout western history, the modern approach of

positivism was described by Auguste Comte in the early nineteenth century who argued that society, much like the physical world operates according to general laws (Macionis, 2012). Tacq (2011) explained that the term positive meant something that is real, has used, and can be measured. This implies that understanding the context of facts was not the primary focus. There is independence between the researcher and what is being studied. Given this ontology, the positivistic methodology is propositionally based – that is being driven by formulation and testing of hypotheses (Creswell, 2014; Crook & Garratt, 2011; Easterby-Smith et al., 2015; Guba & Lincoln 1994). However, as stated by Schmaus (2008), research under positivism did not completely abandon contextual considerations because the sense of discovery still connoted the sense that researchers are the discoverers.

Emerging from positivism, the post-positivistic paradigm assumes that reality can only be comprehended imperfectly and probabilistically, and it can never be fully captured (Guba & Lincoln, 1994). While positivism emphasizes the independence between the researcher and the researched person or object, postpositivism accepts that the background, knowledge, theories and values of the researcher can influence what is observed and understood (Robson, 2002). While also embracing hypothesis testing, the focus of postpositivism is on finding out the context of the cause, and it is achieved from using multiple sources of evidence (called triangulation) such as data sources, theoretical perspectives and methods (Creswell, 2014).

To assess the rigor of positivistic and postpositivistic research studies, four quality criteria are often used. They are reliability, validity, replicability and generalizability (Creswell, 2014; Wahyuni, 2012). Reliability refers to the consistency of the measures that are used to define the constructs. Validity refers to the extent to which the construct measures what it is required to measure. Replicability refers to the ability of research being repeatedly conducted while obtaining similar outcomes. Lastly, generalizability refers to the extent to which the results can be generalized to the wider population (Crook & Garrett, 2011; Wahyuni, 2012).

3.2.2 Constructivism

Unlike positivist epistemology, constructivist epistemology holds that scientists construct knowledge; constructivist ontology opposes the positivist ontology of reality being singular and objective (Creswell, 2014; Guba & Lincoln, 1994). Constructivism, also known as interpretivism, assumes that knowledge is socially constructed, that the meanings of subjects are developed based on information and knowledge gained by the researcher from experience. Constructivists set theories, strategies, or knowledge claims instead of starting with an approach for testing (Creswell, 2014). In a constructivist case study, a researcher tries to understand a social phenomenon through the objects people assign to it (Myers, 2003; Walsham, 1995). The credibility of the story assesses the quality of a constructivist case study unfolded by the researcher (Myers, 2003).

3.2.3 Pragmatism

Another emerging paradigm gaining popularity, particularly among research students is pragmatism (Creswell, 2014). Depending on the area of study and the researcher, pragmatism is a framework for recognizing the value of “the application” rather than the ontology and the epistemology (Creswell, 2014; Rorty, 1991). Pragmatism involves applications or research questions and answers instead of specific paradigm-locked methods (Creswell, 2014; Tashakkori & Teddlie, 2010; Wahyuni, 2012). One of the key principles of pragmatism is that philosophical activity should focus on answering the problems and not forming paradigms (Tashakkori & Teddlie, 2010). Pragmatism resonates well with research designs that involve a mix of qualitative and quantitative data (Creswell, 2014); which sequence data should be collected in mixed method designs (i.e. qualitative fist, quantitative first, or parallel) depends on how best the research questions could be answered via pragmatism (Creswell, 2014).Table 3-1 demonstrates the significant differences between positivism, constructivism, and pragmatism.

Table 3-1 Differences Among the Three Philosophical Approaches (Andrew, Pedersen, & McEvoy, 2011)

Philosophy	Positivism	Constructivism	Pragmatism
Type of research	Quantitative	Qualitative	Mixed
Methods	Closed-ended questions, pre-determined approaches, numeric data	Open-ended questions, emerging approaches, text and/or image data	Both, open and closed-ended questions, both, emerging and predetermined approaches, and both, qualitative and quantitative data analysis
Research practices	Tests or verifies theories or explanations Identifies variables of interest Relates variables in questions or hypotheses Uses standards of reliability and validity Observes and then measures information numerically Uses unbiased approaches Employs statistical procedures	Positions researcher within the context Collects participant-generate meanings Focuses on a single concept or phenomenon Brings personal values into the study Studies the context or setting of participants Validates the accuracy of findings Interprets the data Creates an agenda for change or reform Involves researcher in collaborating with participants	Collects both, qualitative and quantitative data Develops a rationale for mixing methods Integrates the data at various stages of inquiry Presents visual pictures of the procedures in the study Employs practices of both qualitative and quantitative research

3.2.4 The Research's Paradigm

From the four research questions it may become apparent to the reader that the researcher's paradigm is, post-positivism. The researcher has used different data sources, different methods, and different theoretical positions in this research

whist staying within the post-positivistic ontology of singular reality. Post-positivism was selected due to the following benefits (Creswell, 2014).

- It allowed the researcher looking into both quantitative data and qualitative data, which can take the best of both worlds: the inferencing power of quantitative data and rich contextual nature of qualitative data.

- It provided a practical and results-oriented method (Creswell, 2014; Johnson, 2007), without being overly pragmatic (the researcher considers ontology and epistemology as important elements of research practice).

- It allowed the researcher to choose appropriate methods to achieve each research objective, within the board framework of singular objectivity.

3.3 INTRODUCING THE CASE STUDY

This section covers the methodology adopted to answer the first three research questions, which revolve around the applicability of SPC in a PCM environment (see Section 1.3 for research questions).

3.3.1 An Overview of the Case Study Organisation

The organisation covered in this study is one of the largest privately-owned PCM in New Zealand. The company specialises in complementary healthcare products and natural health products. The facility is licensed by the Therapeutic Goods Administration and New Zealand Medicines and Medical Devices Safety Authority. The activities of the case study company include manufacturing, testing and packing of capsules (soft gel and hard shell), dry blended tablets (coated and uncoated). There are over 200 permanent staff employed in the company. In addition, there is floor-level staff who work temporality on working holiday visas, who do not form part of the organisational culture due to their limited affiliation to the company.

The organisational structure of the company is shown in Figure 3-1. A feature in this large company is that each team works as an independent group. This means that a TQM related survey questionnaire administered on each team (other than sales, marketing, and human resources who do not directly contribute to the production/ value addition or quality assurance) provides the same advantage of conducting a survey across multiple organisations.

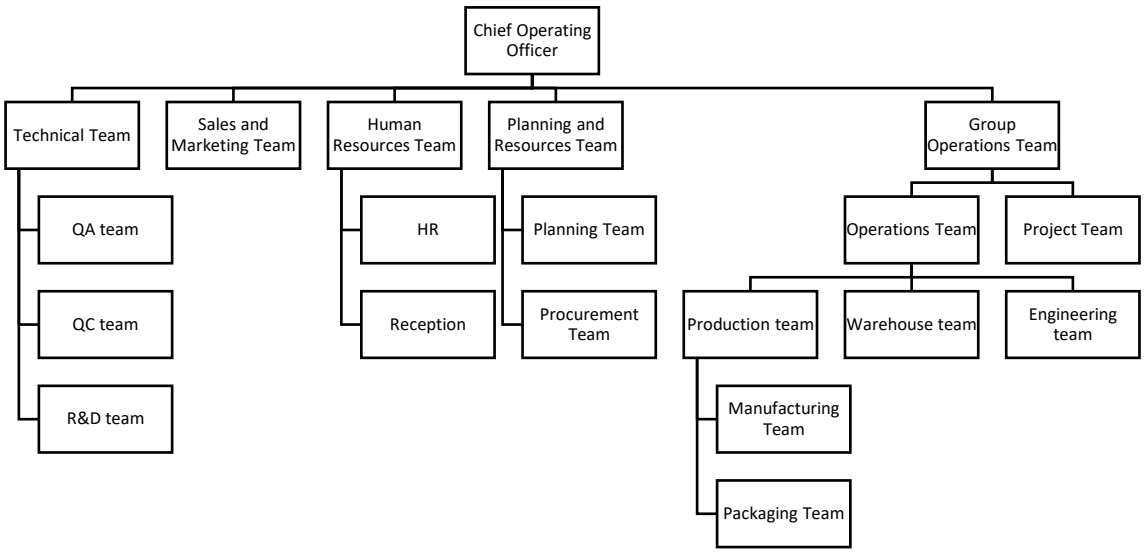


Figure 3-1 The organisational structure of the case study company

Even though the company is light on classical quality control applications (see Section 3.3.2), the culture of the company is conducive to quality improvement, in spite of a seasonal labour force that does not necessarily share the core values and norms of the company. The managers are supportive of quality improvement initiatives that originate at lower levels, such as suggestions for product and process improvement. The managers are appreciative of the fact that operators are not passive entities who do what they have been told to do. The managers recognise that operators are able to contribute in a meaningful way to satisfy the customers by way of helping the company to provide the right product (design quality and conformance quality) at the right time, at the right price, at the right place (distribution). Consequently, the sales and marketing team is an important functional area in this company. There is also cohesion and comradery among permanent staff, particularly at the functional level.

3.3.1.1 Potential Barriers for Quality Improvement

Despite its favourable culture for quality improvement, there seem to be few barriers that seem to hinder quality improvement. Firstly, at the present point in time, floor-level operators appear to be having less information required to implement TQM interventions relative to their managers. However, it must be said that this is not inherently wrong because the existing quality control procedures do not require a great deal of information and analysis on the part of the operators. Secondly, some staff, especially the ones who work on a temporary basis (most notably, the ones on working holiday visas) do not have the same level of motivation compared to permanent and semi-permanent staff to perform. Thirdly, quality issues on products and services of the company attract the attention of top managers, and they take tactical action before quality or customer-related problems escalate.

Top management executives assume responsibility for quality-related performance. They set objectives for quality-related performance and specific quality goals to the company and participate in the quality improvement process. Thus, top management decision making has a direct impact on quality performance. While direct involvement in quality improvement is part of the organisational culture, one could argue that people who are most knowledgeable about problems associated with processes are the people who work at the grass roots such as floor workers (Deming, 1986; Summers, 2010). Thus, the researcher feels that more bottom-up information flow towards quality improvement is desirable for the company.

3.3.2 Exiting Quality Control Procedures

The company analyses product quality as per product formula and specification, which summarised all the requirements from the customer and the regional regulatory bodies. There are various types of pharmacopoeia such as Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (Ph.Eur), International Pharmacopoeia (Ph.Int) and Japanese Pharmacopoeia (JP) in different parts of the world.

Pharmacopoeia is a book published by a competent authority outlining a list of medicinal drugs and their effects and directions for their use by medical practitioners that come under their jurisdiction. In particular, a pharmacopoeia such as the one applicable to New Zealand, prescribes the specified limits a value should fall in order to be compliant as per the standards (Uddin & Mamun, 2015). The main criteria for the quality of any pharmaceutical products are its safety, potency, efficacy, stability, patient acceptability and regulatory compliance.

Physical parameters of pharmaceutical products that are controlled by in-process quality control tests are moisture content, weight, particle size, hardness, loss on drying, disintegration time, colour, compactness, integrity, and the list goes on, depending on the product. In-process testing allows for identifying problems more effectively (Summers, 2010). In-process testing sometimes identifies a defective product batch, which can be corrected by rework. However, once the batch production process has been completed, this may not be possible. Finished product quality control test for pharmaceutical products are assay, uniformity of content, uniformity of mass, weight variation, friability test, the content of active ingredients, hardness test, disintegration test, dissolution test, etc (Uddin & Mamun, 2015). All the test items for pharmaceutical products are included in pharmacopoeias.

Currently, the use of statistical process control is at a minimum level in the company. For example, the operator draws a run chart to monitor the variability of the weight of the product during the manufacturing process. The weight specification limits are also shown in this run chart (the weights are inspected every 30 minutes). The run chart is used primarily to visually inspect the spread of data relative to specification limits. To put it bluntly, the run charts the operators use are for *information only*, *and not for necessary action*! This defeats the purpose of a visual chart meant for continual monitoring, such as the control chart. The purpose of a control chart is to examine the predictability (stability) of a process, rather than the capability of the process in meeting the specification. For process capability analysis, histograms and numerical capability indices such as the Cpk must be used (Summers, 2010).

The data collected by the operator is not used for any serious data analysis purpose, be it for assessing process stability (i.e., ensuring whether or not the process is in statistical control), process capability, or new product development. Competition in this industry has led to increased pressure on the company to improve yields as well as product quality. Currently, the company does not view heavy use of statistics as a requirement to gain competitiveness. However, it is noted that some staff already have a continuous improvement mindset, although unfortunately, this group (sub-culture) is a minority, having their own, shared values. This sub-culture is very important for the study as much of the success of this research project pivots on the corporation of this group. To test whether SPC driven techniques can improve the performance of the process, a quantitative, real-life SPC implementation mini-journey was embarked by the researcher in the company, with the connivance of the top management (Section 3.3.3).

3.3.3 The SPC Mini-Journey Embarked by the Researcher

Given the background mentioned above (organisational culture and the existing quality control procedures), the researcher decided to engage with the operations staff of the company in embarking on a mini-journey that involves the application of intermediate-level SPC for problem-solving. The purpose of this journey was to evaluate the suitability of SPC in a PCM. The following five steps were followed:

Step 1: A staff keen on engaging in a quality improvement project that involves a “small work improvement team”, was recruited.

Step 2: Existing quality records on nonconformities were taken as the starting point for all team members to appreciate that there is a quality issue that warrants intervention. The existing data (also called baseline data from this point onwards) were analysed, and a key quality problem was chosen for quality improvement.

Step 3: A root cause analysis was conducted using SPC tools (brainstorming, Fishbone diagram, and Pareto Chart) to identify the root causes of the

key quality problem and remedial measures required to eliminate root causes.

Step 4: Given the key quality problem, the team was exposed to the two sets of tools that are important in understanding and reducing variation — Shewhart control charts and process capability histograms and associated process capability assessment metrics — to demonstrate the superiority of the above tools over the quality tools and quality control procedures that the PCM uses currently.

Consequently, process stability and process capability analyses were conducted for the chosen quality characteristic for both baseline data (data before the quality improvement project) and new data (after the quality improvement intervention applied via the project), using relevant SPC charts — more specifically, variable control charts (for stability analysis) and process capability histograms.

Step 5: Team members were requested to reflect upon the new things they learned and provide verbal feedback on the suitability of the new tools and techniques for example, SPC tools and techniques such as control charts, control limits, process capability histograms and process capability indices) that they came across to improve quality. The researcher also acted as an ethnographer, observing the reactions and behaviour of team members, in addition to transcribing notes that come from verbal and nonverbal information and cues.

Step 5 mentioned above is the most critical step in the SPC mini-journey because staff buy-in for SPC and, therefore, the suitability of SPC in PCM is established (or otherwise) in this step.

It is assumed that the findings of the case study are “analytically generalisable” across the PCM industry.

3.3.4 Identifying a Key Product Category to Engage with The Staff on Testing the Staff Buy-in on SPC

Oral solids continue to be the most common dosage form in the pharmaceutical market. Hard-shell capsules are a well-established dosage for drug delivery via the oval route, for example, sedative-hypnotic (Flurazepam Hydrochloride capsules), antibacterial (Amoxicillin capsules) and anti-inflammatory (indomethacin capsules). Hard-shell capsule masks the taste and odour of unpleasant medicinal formulations and can be easily administered. The shell is physiologically inert and easily and quickly digested in the gastrointestinal tract. Hard-shell capsules are cost-effective and easy to manufacture. With high chemical and physical stability, capsules require relatively uncomplicated packaging and less complicated storage and distribution requirements.

According to Wright (2018), the consulting services company “Future Market Insights” forecasts the global oral solid dosage pharmaceutical formulation market to grow from $493.2 billion in 2017 to $926.3 billion by 2027, representing a compound annual growth rate (CAGR) of 6.5%. According to IMS Health, nine out of the top 10 drugs based on monthly prescription volume are oral solid doses and the top-selling drugs by sales figures happen to be oral solid doses.

Customer expectations for high-quality scientific expertise and value-priced services are one of the challenges faced by the pharmaceutical industry (Smith & Martin, 2004). Quality reflects how well the process engineer has translated the customer needs into the physical characteristics of the product (Shewhart, 1931; Iqbal, Grigg, & Campbell-Allen, 2014).

3.3.5 Identifying the Quality Characteristic(s) for SPC

One of the key issues the company experiences is controlling the weight variation of hard-shell capsules (this applies to all formulations). The major denominator for weight variation is the variable fill weight. The fill weight can be calculated using the total weight of a hard-shell capsule minus weight of the empty shell.

Table 3-2 depicts the quality issues associated with high fill weight and low fill weight.

Table 3-2 Implications of Falling Out of the Specification Limits (own work)

Condition	Implication
High fill weight Weight > Upper Specification Limit	The length of the capsule becomes too long; the capsule does not fit the blister card during the packing stage. The capsule cannot lock; leaky capsules; Low yield. The batch cannot meet the expected quantity.
Low fill weight Weight < Lower Specification Limit	The quantity of the active ingredient(s) is insufficient and this may have legal consequences. HSC with a lower fill weight than it is supposed to can cause the gelatin capsule to soften and collapse (Wu, Zhao, & Paborji, 2003). This can delay the release of the active drug.

3.3.6 Capsule Manufacturing Process

The hard-shell capsule consists of a cap-piece that slips over the open end of a body-piece. The shells are supplied empty to the pharmaceutical industry by external suppliers. The contents are formulated and filled into the hard-shell capsules by the pharmaceutical manufacturer. Capsule filling is done using an automatic filling machine. Figures 3-2 and Figure 3-3 depict important parts of an automatic hard-shell capsule filling machine.

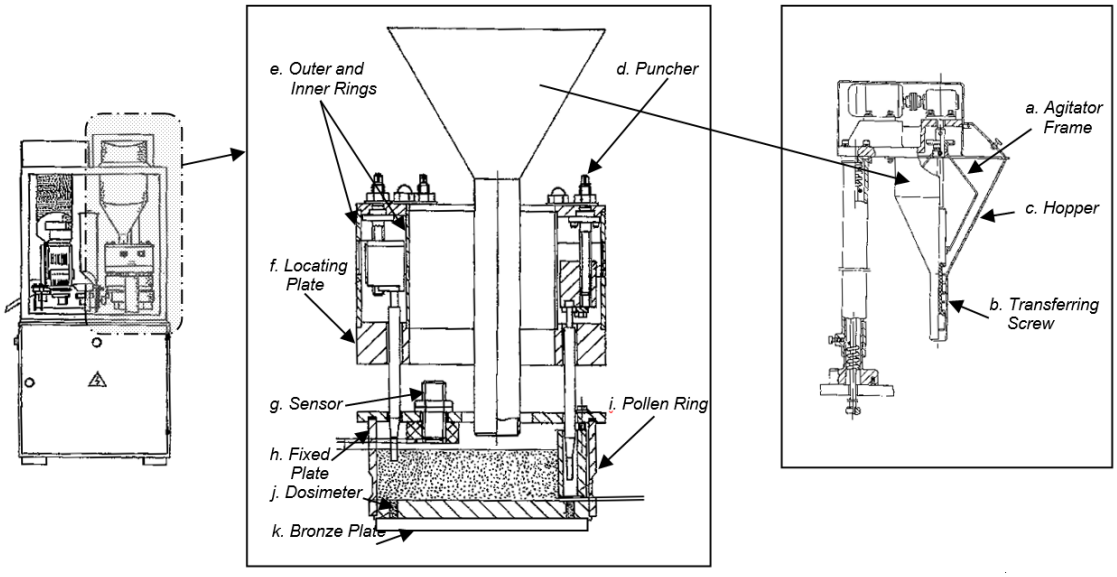


Figure 3-2 A schematic diagram of a capsule filling machine ("Operating & maintenance," 2013)

					
a. Agitator frame	b. Transferring screw	c. Powder hopper	d. Dosing pins	e. Outer and Inner Rings	f. Locating Plate
					
g. Powder sensor	h. Fixed Plate	i. Pollen Ring	j. Dosimeter	k. Bronze plate	

Figure 3-3 Automatic filling machine parts

Figure 3-4 depicts a flow chart for the hard-shell capsule manufacturing process. There is an established four-step process of producing medicinal products, which consists of the following stages: manufacturing, quarantine, testing and release to the market. This practice involves raw and in-process materials testing, manufacturing following an already approved fixed process, and final testing of the finished product to check if it meets its predefined characteristics. The raw materials were weighed and filter through a 20-mesh screen. After blending all mixed raw materials, hard-shell capsules are formed through an encapsulation process using a capsule filler machine, which automatically fills blended powder

into the correct size of hard-shell capsule shells. In all cases, the test for defects or defective products is performed “after the fact” at the end of the manufacturing process or after one of its steps. This inspection practice is also referred to as Quality by Testing (Yu, 2008).

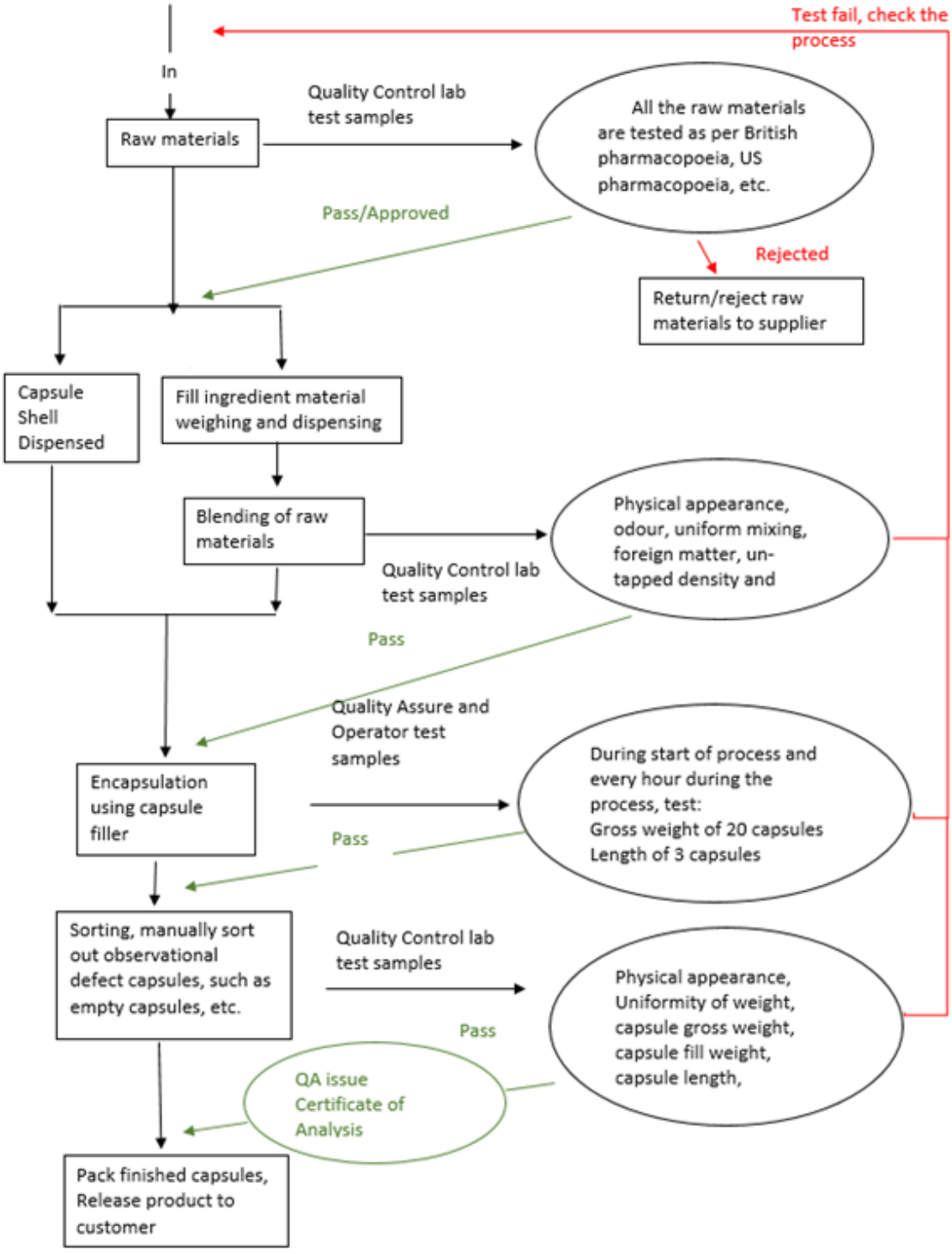


Figure 3-4 Flow chart for hard-shell capsulation process (own work)

3.3.7 Legislation and Enforcement

Under European Pharmacopoeia which the company follows, there is a set of comprehensive quality control tests designed for in-process and finished capsules (Teja, Balamuralidhara, Vinay, Sudeendra, & Pramod, 2011), which include:

- Uniformity of weight
- Content of active ingredients
- Uniformity of content
- Weight variation test
- Disintegration test
- Dissolution test

There are two tests that are related to checking capsule weight. One is the uniformity of weight test, and another is a weight variation test. These two tests are used at different manufacturing stages (Table 3-3).

Table 3-3 Type of Weight-related Quality Control Tests for Hard-shell Capsules

Manufacturing stage	**Type of Test**
Batch process start-up	Uniformity of weight test
In-process	Weight variation test
Batch process finish	Uniformity of weight test

Detailed test procedures for **Uniformity of weight** test are as follows:

1) Randomly select a sample of 20 capsules.
2) Accurately weigh a filled capsule, record it as the gross weight.
3) Open the capsule without losing any part of the shell and remove the contents as completely as possible. Accurately weigh the emptied shell and record this weight as the shell weight.
4) Calculate for the capsule fill weight by subtracting the shell weight from the gross weight (filled capsule eight in Step 1 above).
5) Repeat the procedure for the remaining 19 capsules in the sample.
6) Determine the average weight (i.e. sample mean).

To pass the uniformity of test, the weight of not more than 2 individual capsules would deviate from the average weight by more than the percentage deviation shown in Table 3-4 and none should deviate more than twice that percentage limit given in the table.

Table 3-4 Percentage Deviation for Different Dosage Forms

Average Weight	Percentage Deviation
Less than 300mg	±10 %
300mg or more	±7.5 %

Detailed test procedure for **Weight variation** test, as prescribed in the literature are as follows:

1) At a given point in time isolate 20 capsules for weight testing.
2) Individually weigh twenty filled hard-shell capsules and record the gross weight for each capsule. Determine the average gross weight and record the value. Check the average gross weight against the specification and determine if they conform to the specification.
3) To pass the test, only up to 2 capsules are allowed to exceed the range (from the average) shown in Table 3-4 and none should deviate by more than twice the range given in the table.
4) Repeat the test every hour during the manufacturing process.

3.3.8 Exploratory Analysis

The study aims to investigate an urgent issue in the studied company regarding product quality, and use SPC techniques to investigate the current state of control for a manufactured product and to monitor the process stability. This includes, as mentioned elsewhere, collection and syntheses verbal and nonverbal information that came through the case study participates.

3.4 THE SURVEY QUESTIONNAIRE DESIGN AND PARTICIPANTS

This section describes how the researcher went about in answering her fourth and final research question: what are the enablers of quality performance in a PCM environment, and how do they cause quality performance? Thus, this section covers the enablers of quality performance, the theoretical relationships between these enablers in causing quality performance, and design and administration of the survey questionnaire.

The purpose of administering the questionnaire is to collect data on hypothesised critical factors (enablers) of SPC-led quality performance in a PCM environment, taking the researcher's employer as being representative of a typical PCM. This data were used to statistically test the validity of the hypothesised critical factors (i.e., to establish construct validity) and to identify the present position of the researcher's company regarding hard and soft factors of quality.

It is important to note that the strengths of both hard factors (for example, knowledge of SPC tools, data analytic skills, benchmarking skills) and soft factors dictate what drives and what constrains successful SPC implementation. The case study described earlier provides information on hard factors.

3.4.1 Operationalising TQM to Represent SPC-lead Quality Improvement Climate

Early operationalisations of TQM which is shaped by the teachings of quality advocates such as Deming, Juran, Ishikawa and Garvin emphasised statistical thinking (Ahire, Golhar, & Waller, 1996; Pannirselvam, Siferd, & Ruch, 1998; Hackman & Wageman, 1995; Hoerl & Snee, 2012). While TQM constitutes a set of principles, practices, tools and techniques that focus on continuously improving and sustaining quality of products and services by involving management, workforce, suppliers, and customers to meet or exceed customer expectations, SPC is one of many established management practices that reside within TQM (Cua, McKone, & Schroeder, 2001). Each TQM principle (e.g. fact-based decision-making) accompanies a set of practices (for example SPC is one practice that reflects fact-based decision-making) and each practice (e.g., SPC)

accompanies a set of tools and techniques (Sinha, Garg, & Dhall, 2016; Sousa & Voss, 2002). For example, for SPC, tools and techniques such as control charts, process capability histograms, process capability indices, and other graphical tools such as scatter plots and tally sheets are highly applicable (Summers, 2010). The interlocking nature of TQM principles (for example fact-based decision making cannot happen without cross-functional communication) means that SPC and TQM are intricately related to such an extent that SPC-lead quality improvement climate become inseparable from TQM lead quality improvement climate (Hackman & Wageman, 1995; Sousa & Voss, 2002; Summers, 2010). Consequently, a survey questionnaire that measures acceptance of TQM critical success factors in a PCM environment would also measure the acceptance of SPC in a PCM environment.

SPC, as a technique used within the TQM framework, is particularly useful in the quality control phase, which also acts as a stepping-stone for quality improvement (Juran, 1998; Summers, 2010). The researcher reviewed as many as eleven articles on critical success factors for TQM. The key findings that lead to questionnaire design are shown in Table 3-5.

Table 3-5 Publications Reviewed in Finalising the Questionnaire

Sr	Author(s), Year	Nature of the Article	Key Findings on Critical Success Factors for TQM
1	Saraph, Benson, & Schroeder (1989)	Questionnaire Survey study	Their scale contained measures for the following constructs (CSFs): Management leadership and quality policy; Role of the quality department; Training; Product/service design; Supplier quality management; Process management; Quality data and reporting; and Employee relations.
2	Ahire et al. (1996)	Questionnaire Survey study (Malcolm Baldrige categories)	Their scale contained measures for the following 12 quality management constructs (CSFs): Top management commitment; Customer focus; Supplier quality management; Design quality

Sr	Author(s), Year	Nature of the Article	Key Findings on Critical Success Factors for TQM
			management; Benchmarking; SPC usage; Internal quality information usage; Employee empowerment; Employee involvement; Employee training; Product quality; and Supplier performance.
3	Quazi, Jemangin, Kit, & Kian (1998)	Questionnaire designed from Saraph et al. (1989)	Their scale contained measures for the following constructs (CSFs): Management leadership; Role of the quality department; Training; Product/service department; Supplier quality management; Process Management; Quality data and reporting; and Employee relations.
4	Rao, Solis, & Raphunathan (1999)	Original Research	Their scale contained measures for the following 13 constructs (CSFs): Top management support; Quality information availability; Quality information usage; Strategic quality planning; Employee training; Employee involvement; Product/ process design; Supplier quality; Benchmarking; Customer orientation; Internal quality results; External quality results; and Quality citizenship.
5	Zhang (2000)	Questionnaire designed from literature review	Measures of listed 11 elements (CSFs): Leadership; Supplier quality management; Vision and plan statement; Evaluation; Process control and improvement; Product design; Quality system improvement; Employee participation; Recognition and reward; Education and training; and Customer focus.
6	Motwani (2001)	Literature review	Synthesised the following as CSFs: Top management commitment; Quality measurement and benchmarking; Process management; Product design; Employee training and empowerment; Vendor quality

Sr	Author(s), Year	Nature of the Article	Key Findings on Critical Success Factors for TQM
			management; and Customer involvement and satisfaction.
7	Antony, Fergusson, Warwood, & Tsang (2004)	Questionnaire survey	CSFs in the UK manufacturing industry are (prioritised): Customer focus; Cultural change; Top management commitment and recognition; Communication in company; Continuous improvement; Quality systems and policies; Supervisor leadership; Supplier partnership/ supplier management; Measurement and feedback; and Teamwork and involvement.
8	Das, Paul, & Swierczek (2008)	Questionnaire designed from Saraph et al. (1989)	Measures of listed 10 elements (CSFs): Top management commitment; Supplier quality management; Continuous improvement; Product innovation; Benchmarking; Employee involvement; Reward and recognition; Education and training; Customer focus; and Product quality.
9	Gaddene and Sharma (2009)	Questionnaire designed from literature review	Key factors including: Benchmarking and quality measurement; Continuous improvement; Top management philosophy and supplier support; Employee and customer involvement; Employee training and Efficiency improvement.
10	Koh and Low (2010)	Questionnaire designed from literature review	Customer management; Top management leadership; People management; Process management; Continual improvement; Quality information management; Supplier management; and Organisational learning.
11	Mehralian, Nazari,	Questionnaire designed from	CSFs which are crucial for successful implementation of TQM in the

Sr	Author(s), Year	Nature of the Article	Key Findings on Critical Success Factors for TQM
	Rasekh, & Hosseini (2016)	Literature review	pharmaceutical industry are: Information and analysis; Management commitment; Relationship with supplier; Customer focus; Human resources management; Benchmarking; Quality assurance; and Process management.

3.4.2 Development of the Hypotheses

To develop the hypotheses, the researcher considered each of the following Critical Success Factor of TQM synthesised from the literature summarised in Table 3-5.

3.4.2.1 Information and Analysis

The first area that affects the success of TQM implementation in the pharmaceutical and other industries is inadequate deployment of information and analysis (Mehralian et al., 2016). To keep and promote quality constantly, organisations need a continuous flow of reliable information (Rao et al., 1999; Summers, 2010). In TQM, the usage of information by the management and employees to improve and sustain quality is as important as making information available to all individuals who have a stake in value adding processes. Unfortunately, this is rarely seen in organisations due to hierarchical reporting structures found in PCMs (Lobo, Samaranayake, & Subramanian, 2019; Summers, 2010). Therefore, the first hypothesis of the research is

H1: In a PCM environment, frontline workers have less access to quality-related data than their managers.

3.4.2.2 Top Management Commitment

Today is a highly competitive, rapidly changing global economy forces organisations to use more creative and innovative management methods than before (Mehralian et al., 2016). According to the literature (e.g., Beer, 2003; Vouzas & Psychogios, 2007), top management commitment is one of the most critical factors for TQM implementation success and product quality improvement (Dubey et al., 2018; Summers, 2010). Top management commitment, as well as efficient and visionary leadership, set the foundations for the implementation of TQM in an organisation (Thiagarajan & Zairi, 1997). Top management provides direction, facilities TQM processes by allocating resources, provides guidelines and feedback for employees to achieve organisational objectives via continuous improvement products and processes (Singh & Sushil, 2013). The management must set the direction, commit the budget and resources, provide continuous feedback and progress updates. Then and only then smooth progress of SPC implementation eventuates. If this does not happen, the organisation should not probably adopt SPC (Lim & Antony, 2019; Prasad & Tata, 2003).

3.4.2.3 Customer Focus

As customers become more sophisticated and the competition increases, the customer focus becomes more critical (Hayes, 2018). Companies are obsessed with meeting and exceeding customer expectations; these expectations are also known as “expected quality” (Evans & Lindsey, 2005). A PCM should identify these needs and expectations and translate into product specification.

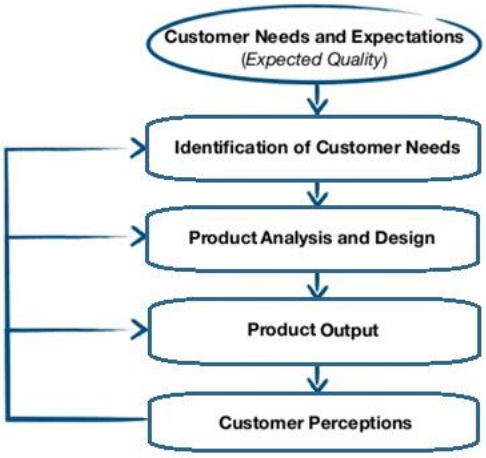


Figure 3-5 Customer-driven quality cycle (Source: Evans & Lindsay, 2005)

A term that is directly related to product specification, which reflects the voice of the customer, is the "quality characteristic" (Rao et al., 1999; Summers, 2010). A quality characteristic of a product is an important characteristic of a product that can be measured or assessed for conformance (Summers, 2010). When the product's quality characteristic is unable to meet the specification, the customer becomes dissatisfied, resulting in complaints, re-work, loss of customers, and losses in the company bottom-line. Figure 3-5 depicts a customer-driven quality cycle that explains the importance of being a customer-focused PCM that continuously updates product specification and effects process improvement. With top management commitment, quality performance can be achieved through customer focus and process management.

3.4.2.4 Human Resource Management

Employee participation at all levels is the key to the successful implementation of TQM. This is because this helps to increase the flow of information and knowledge and will contribute toward resolving problems and well as employee motivation (Teo, Le Clerc, & Galang, 2011; Vouzas & Psychogios, 2007). The critical importance of employee involvement comes from the fact that the best process, innovation, and ideas come from the front-line employees who are doing the job (Patterson, West, & Wall, 2004; Thiagarajan & Zairi, 1997; Vidal, 2006). For TQM to succeed, the entire workforce must acquire specific knowledge, skills, and abilities to enable employees to have greater involvement in the

organisation's quality processes (Patterson et al., 2004; Thiagarajan & Zairi, 1997). Empowerment of employees provides authority and autonomy to employees working at various levels in the organisation. This gives them a sense of pride in workmanship, self-improvement, self-inspection and innovative ideas (Patterson et al., 2004; Thiagarajan & Zairi, 1997). Empowered employees are also required as self-managing teams, self-directing teams, or by autonomous groups in different organisations (Thiagarajan & Zairi, 1997; Vidal, 2006). Empowerment will give employees a sense of belonging toward the organisation and will work in more zealous and innovative ways.

In the knowledge economy, human capital is the most important competitive resource of organisations (Mehralian, Rajabzadeh, Sadeh, & Rasekh, 2012). Consequently, the process of employee recruitment, selection and training have become the most challenging issue of human resource management departments (Mehralian et al., 2012; Singh, 2018). Employees at all organisational levels must be involved in quality improvement programmes. Organisation-wide participation in quality improvement will motivate employees to propose ideas leading to continuous improvement of processes and outcomes such as product quality improvement (Reilly & Williams, 2016; Zhang, Waszink, & Wijngaard, 2000). TQM should provide an open culture for teamwork and continuous quality improvement so that employees can distribute and share knowledge about the quality of products (Ooi, 2012; Reilly & Williams, 2016). From this point of view, knowledge management systems (KMS) for empowering the employees is crucial for successfully implementing TQM. Moreover, empirical evidence suggests that KMS should provide the knowledge needed by employees to stay on top of their ongoing tasks (Akhavan, Rahimi, & Mehralian, 2013; Mehralian, Nazari, Akhavan, & Rasekh, 2014).

3.4.2.5 Benchmarking

Benchmarking is important because it allows companies to improve their performance by learning competitors in the market. The pharmaceutical industry is highly regulated compared with other industries (Mehralian, Rasekh, Akhavan,

& Ghatari, 2013), and therefore, the industry must follow many standards and regulations to be able to operate in the market. In this regard, pharmaceutical companies try to benchmark their key critical business processes against the best practices of the industry. Furthermore, benchmarking encourages employees to use new ideas, methods, procedures and processes, and act as a catalyst for improving the business processes (Huang, Lee, Chiu, & Yen, 2015; Nwabueze, 2012).

3.4.2.6 Quality Assurance Activities

Quality assurance increases the confidence of companies in the quality of products before releasing them to the market (Botet, 2016; Orlandini et al., 2015). The assurance covers the entire supply chain from raw material to finished product, labelling and packaging.

3.4.2.7 Process Management

Process management achieves quality assurance through a periodic review of all aspects of manufacturing operations and consistent corrective actions (Khanna, Sharma, & Laroiya, 2011; Summers, 2010). For this, the critical processes must be identified and improved continuously until better quality products can be released (Summers, 2010).

Based on the above working definitions of the CSFs of TQM, the CSFs can be arranged in a causal predictive framework represented by the mediation model shown in Figure 3-6. Top management emerges as a driver of other elements, and it is an exogenous variable, which has both a direct and indirect impact on quality performance. Leadership should lead to strategic project selection and the use of improvement specialists. These two elements, in turn, enable the use of the structured method for process improvement. Finally, the structured method leads directly to improved organisation performance. Table 3-6 (also Figure 3-6) shows the specific hypotheses, which will be subjected to empirical testing using a path modelling approach (more about this later).

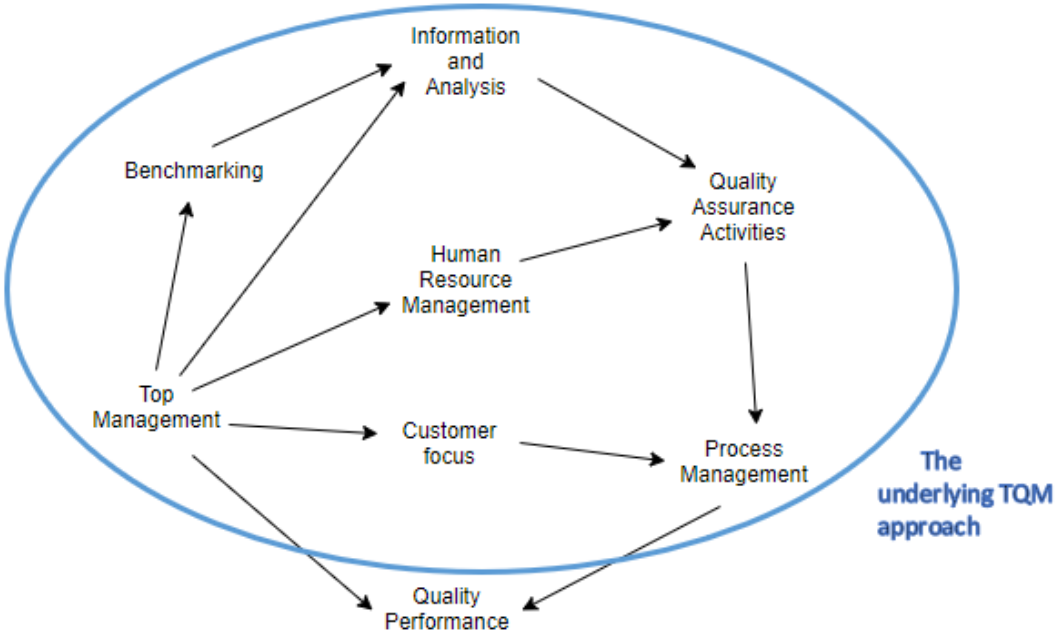


Figure 3-6 The theoretical model underlying the TQM approach to achieve quality performance

Table 3-6 Hypotheses that Constitute the Theoretical Model Shown in Figure 3-6

Hypothesis No.	Hypothesised Path based on the Eleven Pieces of Literature Reviewed (Table 3-5)
H_{SEM1}	Top Management has direct positive impact on Quality Performance
H_{SEM2}	Top Management has direct positive impact on Benchmarking
H_{SEM3}	Benchmarking has direct positive impact on Information and Analysis
H_{SEM4}	Top Management has direct positive impact on Information and Analysis
H_{SEM5}	Information and Analysis has direct positive impact on Quality Assurance Activities
H_{SEM6}	Top Management has direct positive impact on Human Resource Management
H_{SEM7}	Human Resource Management has direct positive impact on Quality Assurance Activities
H_{SEM8}	Top Management has direct positive impact on Customer Focus
H_{SEM9}	Quality Assurance Activities has direct positive impact on Process Management
H_{SEM10}	Customer Focus has direct positive impact on Process Management
H_{SEM11}	Process Management has direct positive impact on Quality Performance

3.4.2.8 Soft TQM factors Vs Hard TQM Factors as Contributors to Quality Performance

The critical success factors of TQM are defined and classified into soft and hard factors due to theoretical reasons (Calvo-Mora, Picón, Ruiz, & Cauzo, 2014).

Soft factors are factors which are hard to acquire or modify. This is because soft TQM factors are intricately related to people and their tacit skills (Dubey & Gunasekaran, 2015; Lewis et al., 2006). To a great extent, soft factors are latent in nature. Soft factors include social and behavioural aspects such as organisational culture (the way activities are being organised and done in an organisation), leadership/top management commitment, human resources or customer and stakeholder orientation.

Hard factors on the other hand relate to the technical aspect of the quality management system such as quality planning, continuous improvement, supplier management, processes management (monitoring and control included), physical resources, information management, and products and services design (Dubey & Gunasekaran, 2015; Lewis et al., 2006). Unlike soft factors, hard factors are easy to acquire or modify (Jayamaha et al., 2014).

Samson and Terziovski (1999) argued that most soft TQM elements affect quality performance. Rahman and Bullock (2005) demonstrated that soft factors of TQM have direct effects on the implementation and utilisation of hard TQM elements. Jayamaha et al. (2014) argued that soft factors required in quality indirectly affects an organisation's outcomes through its effect on hard TQM elements, which is consistent with the researcher's theorisation (Figure 3-6). The above propositions can be summarised by concatenating hard factors, soft factors and Quality Performance in a causal predictive fashion as shown in Figure 3-7.

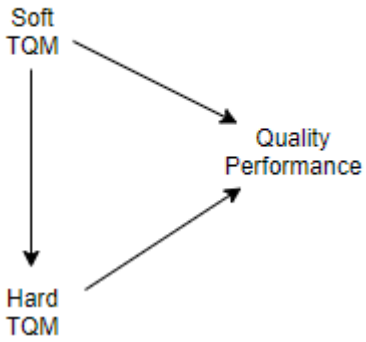


Figure 3-7 Relationship among constructs Soft TQM, Hard TQM and Quality Performance

As the hard factors of TQM include a wide range of techniques, systems and tools, the soft factors are sometimes the missing link that makes TQM paradigm less successful. This leads to the third hypothesis:

H2: Soft TQM factors contribute more to quality performance compared to hard TQM factors.

3.4.2.9 Visa type as Factor Affecting Quality Performance

Working holiday visa holders are being employed heavily in floor-level skilled work in the company under study. They walk straight into the job without any similar previous employment experience under their belt. In New Zealand, working visa holders are only entitled to work in a designated employee role for 3 to 6 months in the specified in the visa (Reilly, 2015). As mentioned earlier, the workers on working holiday rarely become part of the culture of the company, which has the potential to constrain quality improvement. This leads to the third hypothesis:

H3: Operators with working holiday visas participate less in quality-related decision making.

3.4.3 Development of the Survey Questionnaire

The survey questionnaire (Appendix – B) consists of two parts. Part A of the questionnaire covers information about the respondent. Part B covers 46 statements related to the production environment of the respondent's manufacturing facility; these statements can also be treated as statements reflecting the quality improvement climate of the respondent's organisation, based on the CSFs of quality improvement identified earlier. The 46 statements have been developed from the study conducted by Mehralian et al. (2016) due to the following reasons:

- It is a validated questionnaire;
- It is comprehensive. For example, the authors consider many discrete elements of TQM (i.e., many constructs) and the context is pharmaceutical.
- It identifies and prioritises the CSFs within the pharmaceutical industry to ensure successful implementation of TQM; and
- Other researchers in pharmaceutical contexts have used the questionnaire (e.g., Awan, Raouf, Ahmad, & Sparks, 2009).
- Previous scientists have validated the scales in this questionnaire as part of the re-validation of the measurement scales.

Part B of the questionnaire was separated into seven sections to cover all the CSFs of TQM (Table 3-7).

Table 3-7 CSFs Focused on Questionnaire Part B

Sr	CSFs Identified	Soft TQM factor or a Hard TQM factor?	Explanation/ Implication
1	Information and Analysis	Hard	Information and analysis as a tactical factor, is crucial for TQM's leaders as it enables all levels across the organizations to be highly informed about organisation's policies and strategies. To keep and promote quality constantly, organisations need a continuous flow of reliable information (Rao et al., 1999). Usage of information by management and

Sr	CSFs Identified	Soft TQM factor or a Hard TQM factor?	Explanation/ Implication
			employees about the quality status is as important as making this information available to all individuals throughout the organisation.
2	Top Management Commitment	Soft	Top management provides direction, facilities, guidelines and feedback for employees to achieve organisational objectives in continuous improvement of the quality of products and services (Singh & Sushil, 2013).
3	Customer Focus	Soft	Factors such as cost, delivery, flexibility and service related to customers satisfaction but the weight of these factors affecting customer satisfaction might vary from one industry to another (Rajabzadeh, Mehralian, Zarenezhad, & Rasekh, 2013).
4	Human Resource Management	Soft	Knowledge management systems (KMS) for empowering the employees is crucial as the empirical evidence suggests that KMS should provide the knowledge needed by employees to stay on top of their ongoing tasks (Akhavan et al., 2013; Mehralian et al., 2014).
5	Benchmarking	Hard	Not limited to following standards and regulations. Pharmaceutical companies try to benchmark their key critical business processes against the best practices of the industry. Furthermore, benchmark encourages employee to use new ideas, methods, procedures and processes and act as a catalyst for improving the business procedures (Nwabueze, 2012).
6	Quality Assurance	Hard	Quality assurance covers the entire supply chain from raw material to finished product, labelling and packaging. This increases the confidence of companies in the quality of products before releasing them to the market.
7	Process Management	Hard	Process management is a strong tool enhances quality assurance through a periodic review of all aspects of manufacturing operations and consistent

Sr	CSFs Identified	Soft TQM factor or a Hard TQM factor?	Explanation/ Implication
			corrective actions (Khanna et al., 2011). The critical processes must be identified and improved continuously until the better-quality products can be released.

3.4.4 Level of Measurement

In part B of the questionnaire, a 7-point Likert scale was used to seek agreement or disagreement with 46 statements on several facets related to the hypothesis. In the Likert scale that was used, code 1 indicates “Strongly Disagree” while code 7 indicates “Strongly Agree”. Codes 2, 3, 4, 5 and 6 refer to “Disagree”, “Somewhat Disagree”, Neither Disagree nor Agree”, “Somewhat Agree”, and “Agree” respectively. A seven-point Likert scale is used to improve the reliability of the measurement scale (Nunnally & Bernstein, 1994). The scale provides the flexibility to use as many points in the scale considered necessary, and it is also possible to use different anchors. When a neutral point is provided, the scale becomes a balanced rating scale, and when it is not, it becomes an unbalanced scale, which is not generally desirable (Nunnally & Bernstein, 1994). In administering the survey, the anonymity of the respondents was always maintained, and the survey was conducted in accordance with human ethics guidelines of Massey University.

3.4.5 Data Collection

The data for this study was gathered using a questionnaire produced in printed form (hard copies). One hundred fifty copies of the questionnaire were distributed to three departments, which were involved in the decision-making processes: Production department (N = 128), Quality Control department (N = 12), and Quality Assurance department (N = 10). Questionnaire drop-off boxes to collect responses were kept in each department and the respondents were given three weeks to drop-off the duly completed questionnaires in the respective drop-off

boxes in their department. Three days prior to the deadline of survey completion, a reminder was dispatched via the company's bulk emailing system to respond to the survey if anyone has not done so already. Since only one copy of the questionnaire was given to each potential respondent, it was assumed that the responses would come from individuals and that the responses are personal choices rather than consensus choices or choices that have come under duress from the superiors to respond in a particular way (the statistical analysis vindicated this assumption).

3.4.6 Pilot Testing

Testing a survey questionnaire with a small sample[1] prior to launch of the official survey is deemed a good/safe practice (Reynolds, Diamantopoulos, & Schlegelmilch, 1993; Boudreau, Gefen, & Straub, 2001; Burns & Kho, 2015). The primary purpose of pre-testing or pilot-testing a questionnaire is to test whether the survey items are well-drafted (e.g., precise, no near-identical questions) from the point of view of the respondent (Ruel, Wagner, & Gillespie, 2015).

The questionnaire was pilot tested using five respondents playing non-similar roles: quality control technician, quality assurance officer, soft gel area coordinator, dry area manager, and production and quality technician in the packing department. Three respondents were asked to read out the questions loud in front of the researcher and answer the questions thereafter; the three pilot-test participants were given the opportunity to ask questions if anything was not clear to them. Two remaining two respondents were asked to fill the questionnaire silent as if they would respond to any other paper and pencil type questionnaire. The researcher recorded the time spent by each respondent in answering the questionnaire. At the end of the questionnaire, the pilot respondents were asked to add remarks (no more than seven) on the clarity of each question and suggestions that they would like to make on any of the questionnaire items. Overall, the pilot test went well and was very helpful. The data collected from pilot

[1] The sample size does not matter very much as statistical inference tests are not involved in pilot testing.

testing were pooled to the final dataset to increase the sample size. Table 3-8 lists adjustments that were made after the pilot testing.

Table 3-8 Adjustments Made Based on Pilot Testing

Question	Changes
Part A	
Q3	Added “none of above” as a selection option
Part B	
Q31 & Q46	Added examples to explain certain terms/phrases
Q42-Q46	Updated from past 3 years to past 2 years because some recruits in the pilot survey told that they have not been working for 3 years.

3.5 RECRUITING STUDY PARTICIPANTS AND HUMAN ETHICS

Participants involved in the research study are front-line production workers (including the operator, front-line quality inspector and packer), supervisors, team leaders, coordinators and managers from the production team, quality assurance team and quality control team. More detailed participation structure of this research is listed in Table 3-9:

Table 3-9 Participation Structure

Study Phase	Aspect	Participant(s)
SPC Case Study (SPC Mini-journey)	Quality Improvement team	Representative from Quality Assurance team, front line inspector, front line operator and department manager and researcher
	Sample collection	Front line operator
	Tester	Quality Control Team- laboratory technician
	Data analysis	Researcher
Quantitative study to test the hypotheses via survey data	Pilot testing	Quality Control Technician, Quality Assurance Officer, Soft gel area coordinator, Dry area manager, and Production and quality technician works in packing department
	Answering the questionnaire and interview questions	production frontline worker (including operator, front-line quality inspector and packer), supervisors, team leaders, coordinators and managers from Production

Study Phase	Aspect	Participant(s)
		team, Quality Assurance Team and Quality Control Team
	Survey data analysis	Researcher

Important ethical issues were considered during the study. Consent was obtained from the researcher's line-manager before executing the study, and his advice was sought on any potential issues from the point of view of the company or its employees. The aims and objectives of the study were not changed after data collection, and the case study findings were not exaggerated in any way. The data collected, and results obtained were not tampered with and the results were reported with absolute honesty. The SPC case study findings were debriefed to the participants. Neither they nor their managers raised any issues. The study did not involve any form of intervention involving human participants. The study was thus deemed low risk by the researcher and her academic supervisor. Low risk notification is attached as Appendix - A.

3.6 CHAPTER CONCLUSION

This chapter covered the methodology of this research. The chapter covered research paradigms, the background of the case study to embark on a SPC implementation mini journey, development of hypotheses and theoretical models, development of testable hypotheses, development of the survey questionnaire to collect data to test the hypotheses, as well as selection of participants in the case study as well as in the survey. SPC implementation case study data and survey responses for this study were collected from the researcher's employer only due to the limitation of time. This is an obvious limitation. For the statistical analysis, SmartPLS was used to test the hypotheses involving latent variables (i.e., hypothesised path relationships) while Minitab was used for SPC analysis, exploratory factor analysis, and reliability analysis of the measurement scales of the latent variables. SmartPLS adopts the partial least squares (PLS) approach to latent variable path modelling, which is the method of choice when one is dealing with small samples and/or when one has doubts on departures of

parametric assumptions[2] (Chin, 1999; Hair, Hult, Ringle, & Sarstedt, 2014). The alternative, and the more established latent variable path modelling method, the covariance-based modelling requires large samples as well as fulfilment of parametric assumptions such as normally distributed data, which did not eventuate in this study. Hence the covariance method was not adopted.

Figure 3-8 shows the logical flow of the research questions, where the methodology used to answer the research questions are found.

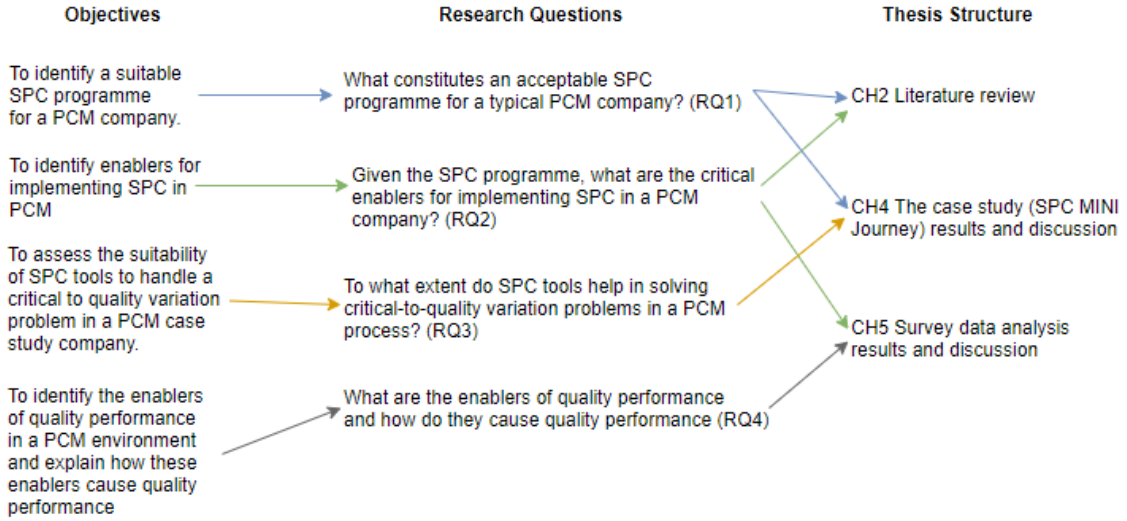


Figure 3-8 A flow chart showing the methods used to answer each research question

The next chapter presents the results of the case study, along with an accompanying discussion.

[2] Statistical inferences on parameters are classically based on the assumption of normally (meaning normally distributed data), independence or observations (hence independence of error terms), and equal variance of errors across the full range of X-Y relationships (Hair et al., 2014). Satisfying these assumptions is often challenging due to practical reasons. For example, when a questionnaire is distributed to a department, there is some dependence of observations because respondents share common perceptions around their working environment. Hence the observations are not genuinely independent.

Chapter 4 THE CASE STUDY (SPC MINI JOURNEY) RESULTS AND DISCUSSION

4.1 INTRODUCTION

This chapter serves two aims. The first is to see how SPC can be used to minimize defects that will reduce rework and rejection rate to justify the application of SPC in the PCM. The second and the more important aim is to use the findings of the case study to answer research questions 1 and 3 (i.e., RQ1 and RQ3). The remaining research questions RQ2 and RQ4 can only be partially answered via the findings reported in this chapter. RQ2 and RQ4 will be more fully answered via the findings reported in the next chapter. For ease of reference, the research questions of this study are restated as follows:

RQ1: What constitutes an acceptable SPC programme for a typical PCM company?

RQ2: Given the SPC programme, what are the critical enablers for implementing SPC in a PCM company?

RQ3: To what extent do SPC tools help in solving critical-to-quality variation problems in a PCM process?

RQ4: What are the enablers of quality performance and how do they cause quality performance?

The quality improvement project was fashioned to conform with the Six-step process of SPC implementation prescribed by Berk and Berk (2000), with the exclusion of Step 4, which is formal training of staff including the management (a not in scope item of the project).[3] For details, the reader may want to refer Section 2.5.2 in Chapter 2 (literature review). Sections 4.2 through to 4.6 cover Berk and Berks' Steps 1, 2, 3, 5, and 6 respectively. Section 4.7 covers what the researcher and case study participants learned from the project. Section 4.8 discusses the findings of the case study in the light of extant literature. Section 4.9 summarises

[3] Informal training took place as described later. See Section 4.4.

the case study findings in relation to relevant research questions. Finally, Section 4.10 provides a summary of key findings of this chapter.

4.2 IDENTIFYING CANDIDATE PROCESS FOR STATISTICAL CONTROL (STEP 1 OF 6)

A Pareto analysis was performed to analyse defect type in the hard-shell capsule manufacturing process. From all the quality issues related to hard shell capsules in 2018, it found that vital defects in hard shell manufacturing were mainly related to product weight variation (Table 4-1). As a pharmaceutical company manufacturing restricted medicines, the company aims to be competitive in the market, but current manufacturing strategies have not provided much of an edge in the market either as a cost-effective manufacturer or a quality leader. It was proposed to the management that SPC could be tried out to add better control over quality to boost the effectiveness of current quality control techniques. This proposal was accepted, when the merits of quality was explained using the famous quote by Crosby: “quality is free”.

Table 4-1 Quality Issues Related to Hard-shell Capsules Manufactured in 2018

Categories	**Number of Batches (Instances) Reported**	**Proportion**
Abnormal colour	2	13%
Foreign particle	1	7%
Length lower than the specification	1	7%
Telescopic capsule	1	7%
Weight issues: under-filled capsules, overfilled capsules and weight variation	7	47%
Empty shell	3	20%
Summary	15	

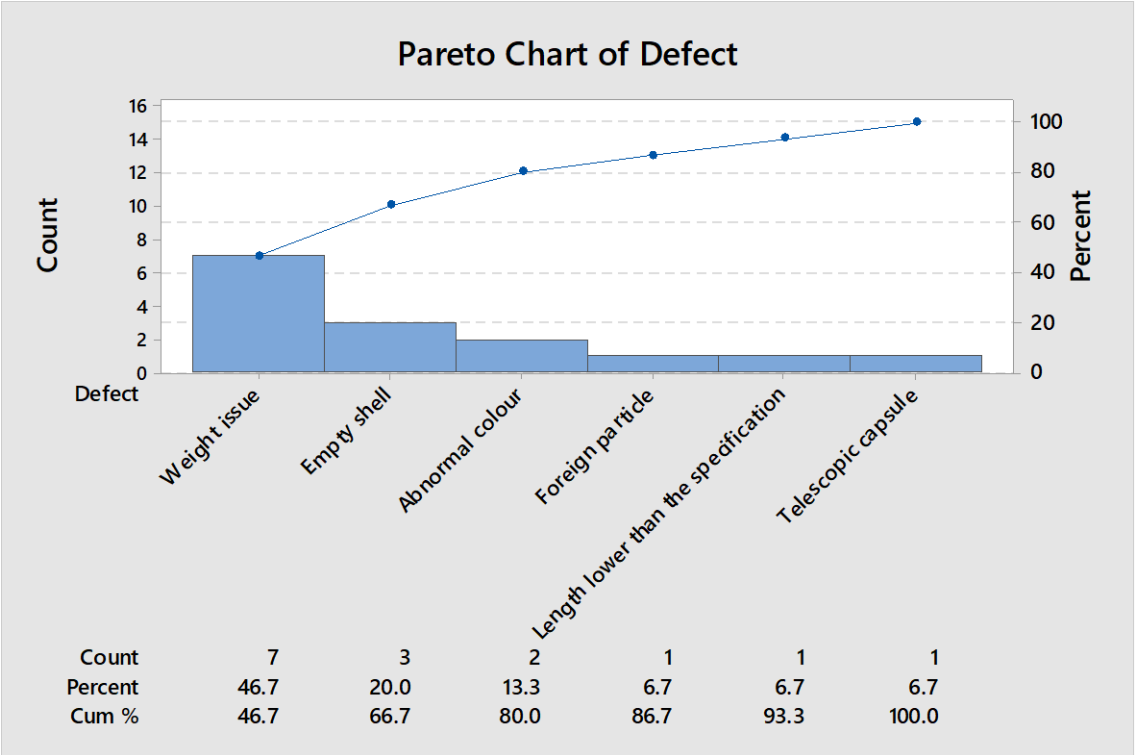


Figure 4-1 Pareto chart to display potential categories of quality issues related to hard shell capsules in 2018

From Figure 4-1, it becomes clear that most prevalent nonconformities relate to fill weight, empty shell, and abnormal colour. Uniformity of weight of the drug is important because this ensures the even distribution of ingredients in the drug. More over there is no guarantee — given the current regime of quality control — that the number of nonconforming batches limit to the ones recorded by the company. In any case, uneven distribution of weight may excessively alter the dosage in each individual capsule and this may lead to problems such as being unable to reach the therapeutic range or exceed the therapeutic range to the point of even reaching the “toxic range”.

The quality improvement team signed-up for the cased study consisted of the team composition shown in Table 4-2.

Table 4-2 The Membership of the Quality Improvement Team

Department	Job Position	Number of staff
Production team	Machine operator	3
	Supervisor	1
	Production quality assurance technician	4

Department	Job Position	Number of staff
Quality Assurance team	Quality assurance officer	1
	Quality assurance coordinator	1
The researcher (convenor/facilitator)		1
Total		11

4.3 FLOW CHARTING THE PROCESSES OF AUTOMATIC FILLING MACHINE (STEP 2 OF 6)

The automatic filling machine orientates, opens the empty hard capsule shell, fills the capsule with ingredients, and automatically closes and locks the capsules (Figure 4-2) (Shah, Augsburger, Small, & Polli, 1983).

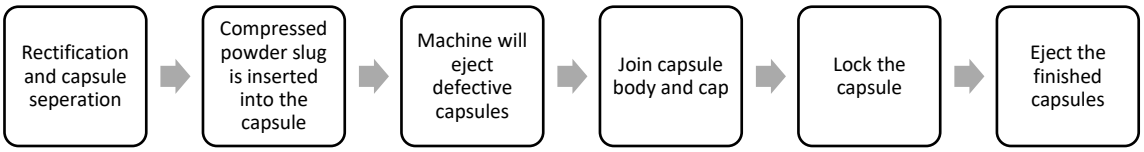


Figure 4-2 Flow chart for hard-shell capsule encapsulation process (Shah et al., 1983)

Empty shells are fed into the capsule hopper and lined up all in the same direction caused by a machine process named rectification. The rectified shells are introduced into a split bushing. The bushing consists of an upper part and a lower part. A vacuum is applied from the bottom piece to cause the body to be drawn into the lower section of the bushing. The cap remains in the upper bushing piece because its diameter is too large to permit it to follow the body piece. The two bushing pieces are then separated to expose the body piece for filling.

In the filling step, the dosing-disc is provided with holes that are closed off by a solid brass “stop” plate that slides along the bottom of the disc to form the dosing cavities. The cavities are indexed under tamping pins at each of five tamping stations. From Figure 4-3, the powder slug is compressed to 1/5 thickness of

dosing disk, then 2/5 and 3/5 (Armstrong, 2008). The powder slug is compressed to the same as the thickness of the dosing disk and finally, the compressed slug of powder is inserted into the capsule (Armstrong, 2008). The formulation is maintained at a somewhat constant level over the dosing-disc (Figure 4-3). A capacitance probe senses the powder level and activates an auger feed mechanism when the powder depth falls below a pre-set level. As the disc rotates (indexes), the formulation is distributed over the disc by centrifugation with the assistance of baffles mounted to the disc. Powder falls into the dosing cavities as they move from one tamping station to the next. Additional powder is pushed into the dosing cavities by the descending tamping pins at each tamping station. Each plug is thus tamped five times. Excess powder over the disc is scraped off as the dosing-disc indexes the plugs to the ejection station, where they are positioned over empty capsule bodies and ejected by transfer pins. For a given formulation, size of tooling and powder depth over the disc, the fill weight achieved is determined primarily by the thickness of the dosing disc and the piston penetration setting (or tamping force) (Armstrong, 2008).

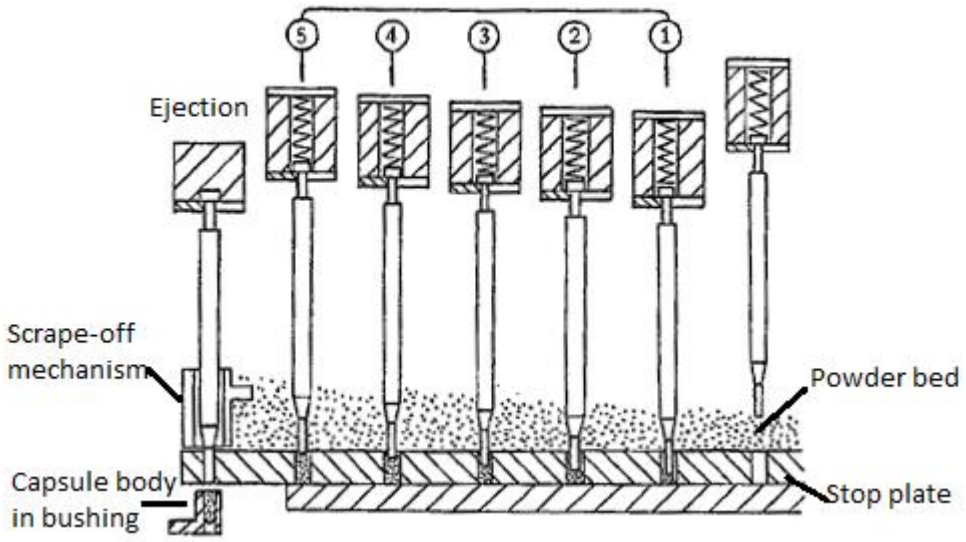


Figure 4-3 Powder slug adjustment ("Operating & maintenance," 2013)

In capsule closure step, the cap and body bushings are brought back together, and the cap and body pieces are re-joined via push pins. In most cases, ejection of the filled and closed capsules from the bushing is caused by push pins.

4.4 IDENTIFYING THE SOURCES OF VARIABILITY (STEP 3 OF 6)

Root cause analysis is a structured team process that assists in identifying variability sources. Understanding the contributing factors for excessive variability or causes of a system failure can help develop actions that sustain the correction. A cause and effect diagram, also known as the Ishikawa diagram or fishbone diagram, can help in brainstorming to identify possible causes of a problem along root causes or categories. It is a more structured approach than some of the other tools available for brainstorming to identify causes of a problem. A cause and effect diagram help the brainstorming team to identify possible causes of a problem that might not otherwise be considered by directing the team to look at the categories and think of alternative causes. It is important to include team members who have personal knowledge of the processes and systems involved in the problem or event being investigated. These requirements were followed in the project. Figure 4-4 depicts a completed cause and effect diagram, which lists all potential causes of capsule weight variation as identified by the Quality Improvement team.

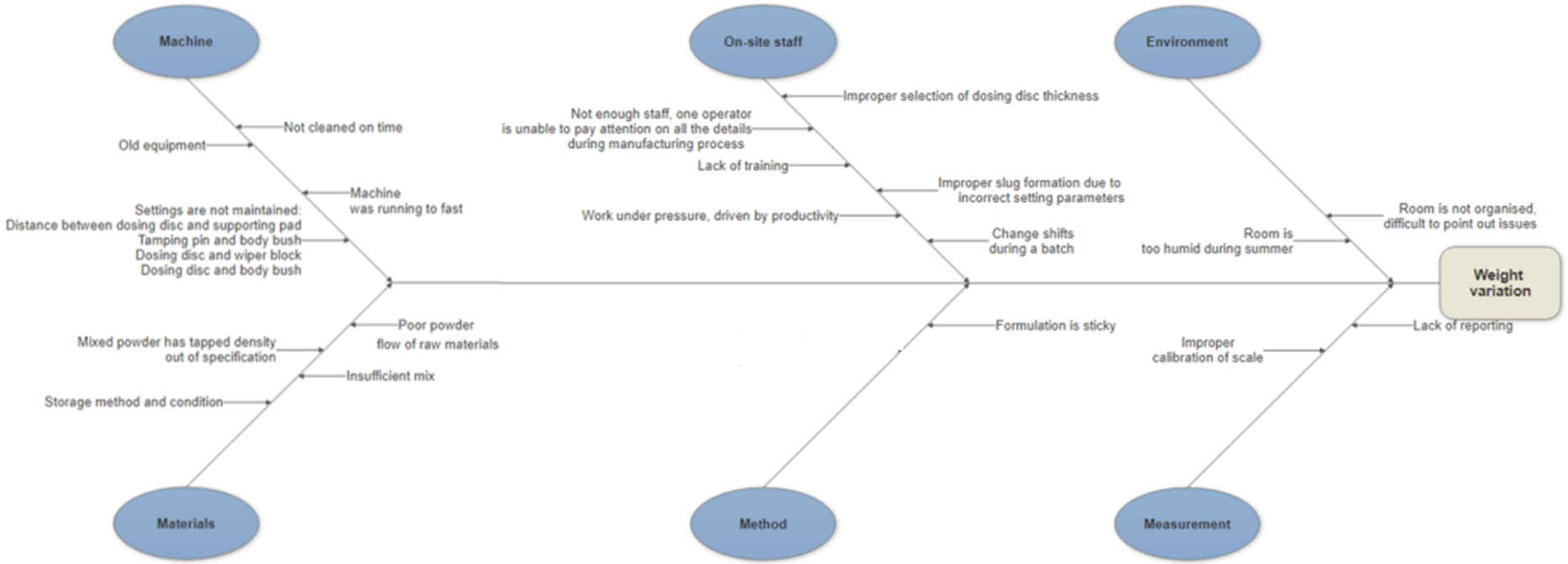


Figure 4-4 Potential causes of capsule weight variation in an Ishikawa diagram

The following recommendations were worked out by the quality improvement team to eliminate the causes:

1) The powder should be well mixed, and the storage environment should conform to stipulated standards.
2) Parameters and conditions of the machine should be constantly checked during the manufacturing process.
3) Operators must perform in-process inspection and setting checks; all the findings should be reported to quality department.
4) The proper environmental conditions should be maintained; the operators should turn on dehumidifier if the room is humid.
5) Staff needs more training.
6) More staff is required.

Training of staff, initially the management and them the operators (Step 4 of 6) is very important for SPC and other continuous improvement methods to sustain (Summers, 2010). However, in this project, the training of the staff (more precisely, training of the staff involved in the quality improvement team) took place informally by dwelling in a real quality improvement problem. The reason for this is the tight time timeframes the research project must work with and want of a formal management decision to implement SPC.

4.5 GATHERING PRELIMINARY DATA (STEP 5 OF 6)

The researcher has labelled the specific product for this study as HSC1, instead of its pharmaceutical name for confidentiality reasons. The data were collected from the same batch (Batch1).

The listed procedures shown below were performed every hour from (batch) start to finish using samples (subgroups) of size 20. Capsules were collected and weighted by the operator, and calibrated digital balance was used to weigh each capsule.

1) Sequentially collect 20 capsules to form a subgroup.
2) Accurately weigh a filled capsule, record the weight as the gross weight.
3) Open the capsule without losing any part of the shell and remove the contents as completely as possible. Weigh the emptied shell and record the weight as the shell weight.
4) Calculate for the capsule fill weight by subtracting the shell weight from the gross weight.
5) Repeat the procedure for the remaining 19 capsules in the subgroup.

A total of 25 subgroups of samples were collected to cover the batch production. The average weight of capsules (the mean of subgroup means, which provide the average weight of 20 x 25 = 500 capsules) was found to be 870.75 mg (so > 300 mg). Therefore, the applicable range (see Table 3.4 in the previous chapter) is 870.75 mg ± 7.5%. Among the 20 capsules, no more than 2 of the individual weights deviated from the above limit and none deviated from 870.75 mg ± 15%, thus passing the test.

For this study, the specification (for weight) was taken as 867.29 mg $\pm$ 7.5%, where 867.29 mg is taken from theoretical long-term average.

4.6 PREPARING AND USING SPC CHARTS (STEP 6 OF 6)

The SPC is the technique that underpins statistical thinking: the science and art of understanding the variation. As Deming and other proponents of statistical thinking advocate, “understanding variation” is the key to success in the quality domain. Minitab was used to analyse subgroup data and to draw SPC charts.

4.6.1 Studying the Stability of the Process Using Control Charts

Because the subgroup size 20 was larger than 8, $\bar{X}$ - S control chart was selected for analysis of data. $\bar{X}$ and S charts show the variation of subgroup mean and standard deviation respectively, over time (Figure 4-5).

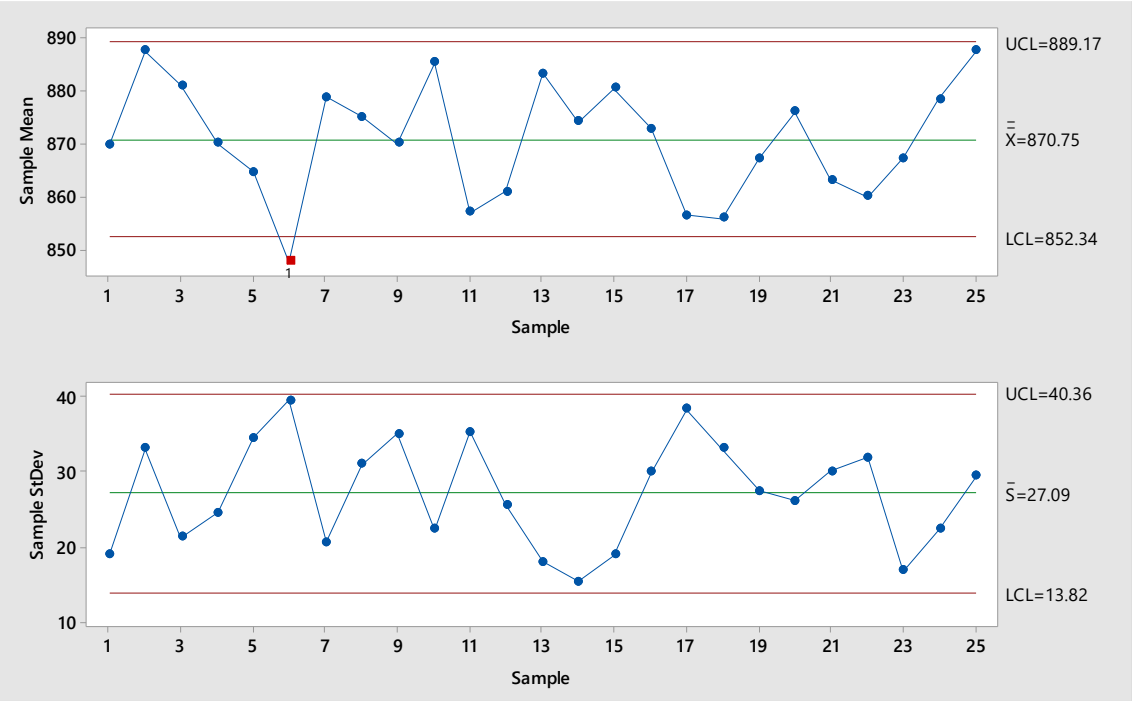


Figure 4-5 $\bar{X}$ - S control chart for capsule weight case study

The standard deviation chart (Figure 4-5) shows that the process variation based on subgroup (sample) standard deviation is in control. All the points fall in the control limits and there are no non-random patterns such as six or more continually rising or falling points (i.e. trends) or 14 points in a row moving up and down (oscillations). The exact same cannot be said about the control chart for subgroup (sample) mean. Below was the message from Minitab:

TEST 1. One point more than 3.00 standard deviations from center line.
Test Failed at points: 6

There was an out-of-control value on the sample mean chart, the value related to sample 6, which shows a sample mean of 847.6 mg. There is strong evidence that the process is out of control at 6h since starting of the batch manufacturing process. This $\bar{X}$ - S chart indicated the process was unstable based on subgroup average (i.e. process being out of control). The operator shift changed just before sample 6 was collected. The operator noticed the abnormal capsule weights and adjusted the machine accordingly, pulling the process back into control.

4.6.2 Studying the Capability of the Process Using Process Capability Histogram and Process Capability Indices

The attention is now turned to process capability analysis. According to the literature, for process capability analysis to be truly meaningful (particularly, Cp and Cpk indices), one should verify that the data for the process has come from a stable process and that the data follow a normal distribution (Summers, 2010). From the process stability analysis, it becomes clear that data belonging to sample 6 should not be included in process capability analysis because sample 6 represents an out-of-control situation. However, process capability analysis was conducted with and without sample 6 (outlier) data because the purpose of this project, in part, was to expose the staff to SPC theory and practice.

4.6.2.1 Process Capability Analysis with Sample 6, the Outlier

The weight specification of 867.29 mg $\pm$ 7.5% translates to an upper specification limit of 932.34 mg and a lower specification limit of 802.24 mg, which is indeed a wide tolerance.

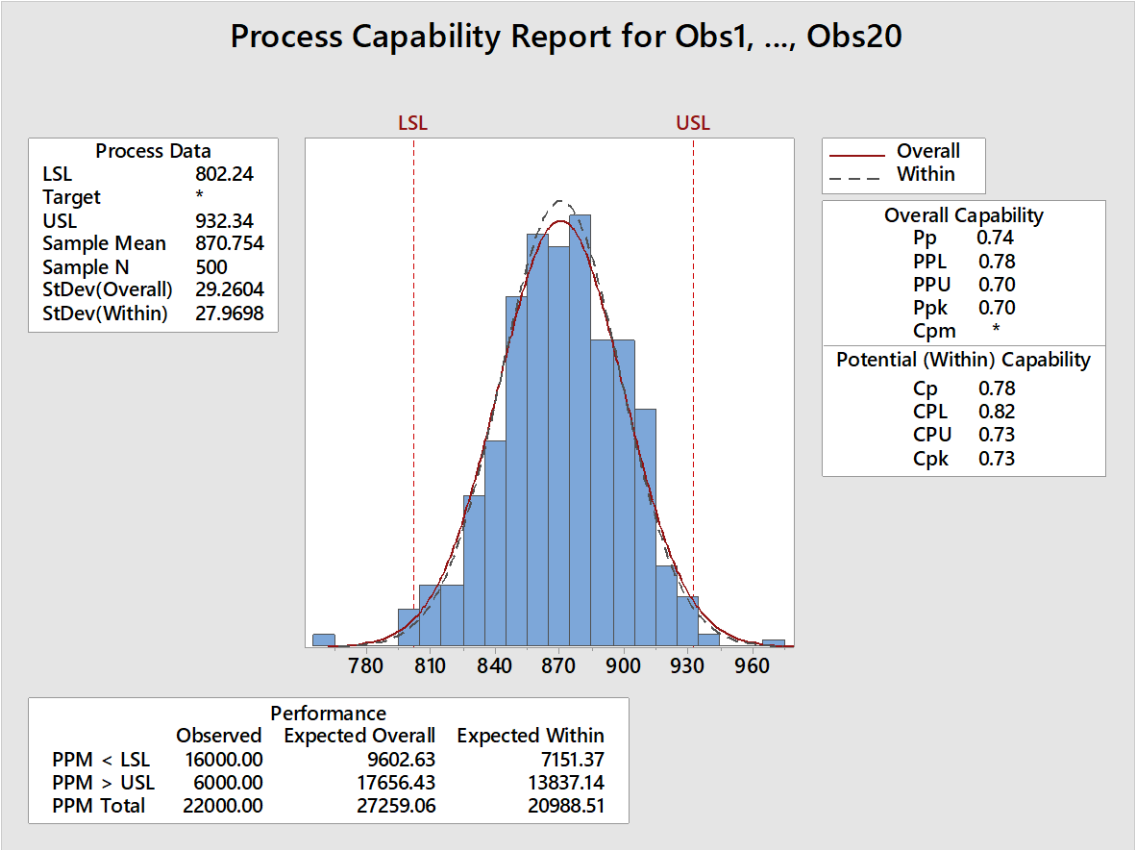


Figure 4-6 Process capability chart for capsule weight case study with sample 6

The process capability histogram (Figure 4-6) shows that the data are approximately normally distributed (more information later). Although most of the data were within the specification limits, there were nonconforming results below the LSL and above the USL.

Table 4-3 depicts the relationship between the Cpk and the defects rate. The figures in this table assumed that the process was perfectly well centred (i.e. the process average being right in the middle of the upper and lower specification limits). In practice, this does not happen over a prolonged length of time because the process average drifts from the so-called ideal target (Rao et al., 1999; Summers, 2010). In six sigma literature, it is stated that in the long run, a process average can drift up to 1.5 standard deviations (i.e. 1.5σ) to either side of the specification limits (Box & Luceño, 2000; Pyzdek, 2003). Under the 1.5σ process drift assumption, a six-sigma level of quality results in a Cpk of 1.5 and a defects rate of 3.4 defects per million opportunities (Pyzdek, 2003).

Table 4-3 Explanation for the Impact of Cpk Values (Source: Oakland & Oakland, 2018)

Cpk	Sigma Level (σ)	% Conforming	Defects Per Million (DPM)	Defect Rate
0.33	1	68.27%	317,311	1 in 3.15
0.67	2	95.45%	45,500	1 in 22
1	3	99.73%	2,700	1 in 370
1.33	4	99.99%	63	1 in 15,873
1.67	5	100.00%	1	1 in 1,000,000
2	6	100.00%	0.002	1 in 500,000,000

Many industries use a benchmark value of Cpk equal to 1.33, and Cpk of 0.73 in this case was much lower than the benchmark. In the project under review, Cp (0.78) and Cpk (0.73) were approximately equal[4], which indicated that the process was centred between the specification limits (Pyzdek, 2003). Ppk (0.70) and Cpk (0.73) were approximately equal too. Because Ppk (0.70) and Cpk are less than 1.33, the overall capability of the process did not meet customer requirements.

[4] It must be kept in mid that Cp and Cpk values need to be recalculated after removing outlier data for the analysis to be very accurate.

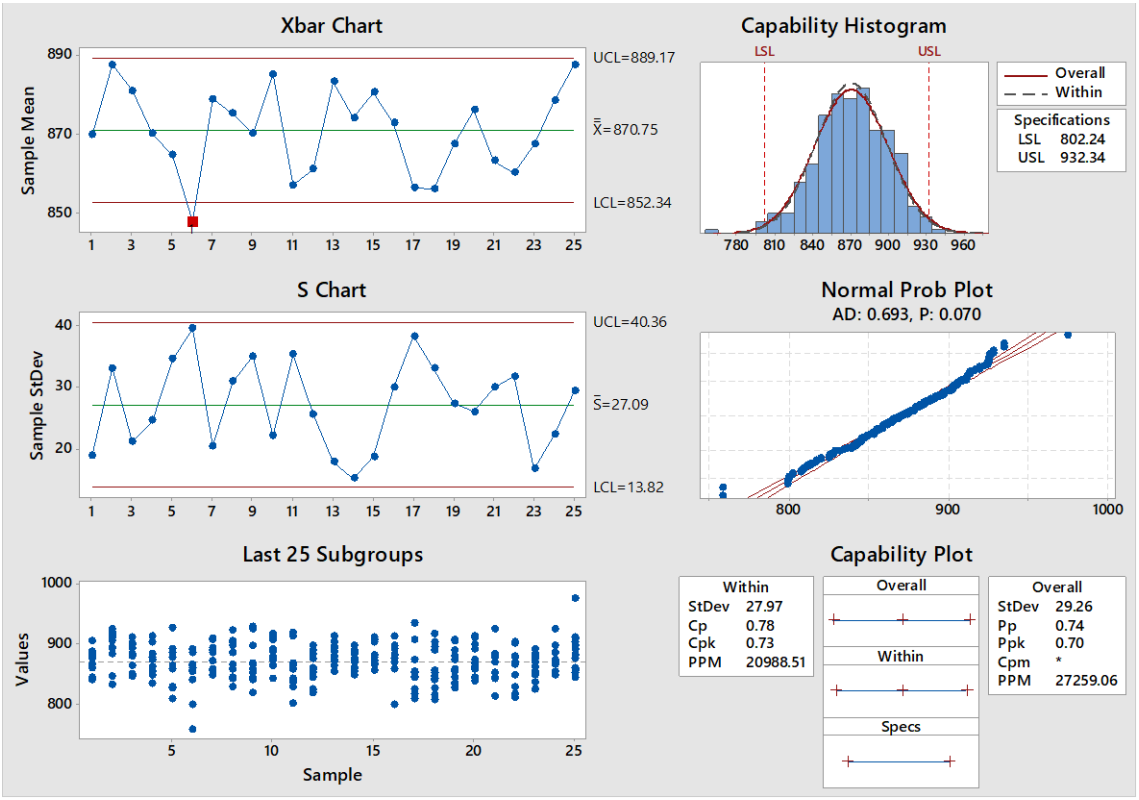


Figure 4-7 Process capability six-pack chart for capsule weight case study

Minitab's process capability six-pack diagram provides a fuller picture of stability and capability of a process within a single diagram. The one relevant to the project, with the outlier (sample 6) included is shown in Figure 4-7. The p-value from Normal Prob Plot (based on Anderson-Darling test) is greater than 0.05, indicating that the data come from a normally distributed population, thus fulfilling the normality assumption used in process capability analysis. The project team was told that the Cp and Cpk results are less reliable when a process is behaving in an unpredictable manner and by all account, the analyst should exclude outlier data.

4.6.2.2 Process Capability Analysis without the Outlier

First and foremost, one must ensure that the process remains stable once the outlier is eliminated. Figure 4-8 clearly indicates that this is the case, for the project under review. The revised, and more accurate process average happens to be 871.72 mg.

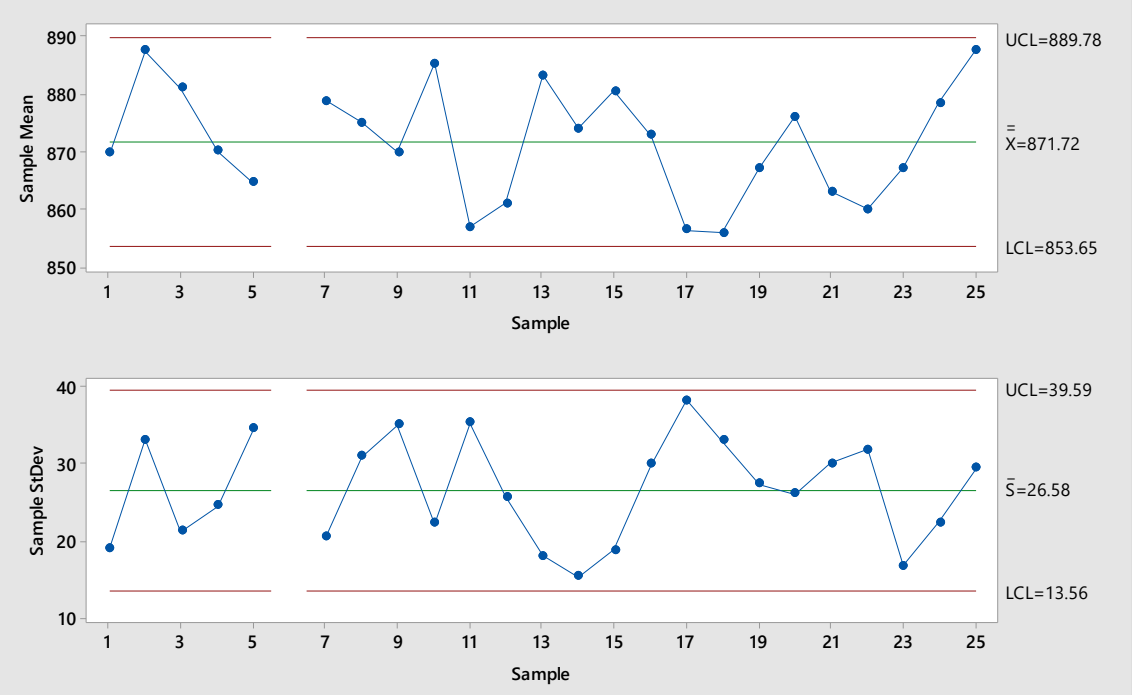


Figure 4-8 $\bar{X}$ - S chart after removing sample 6

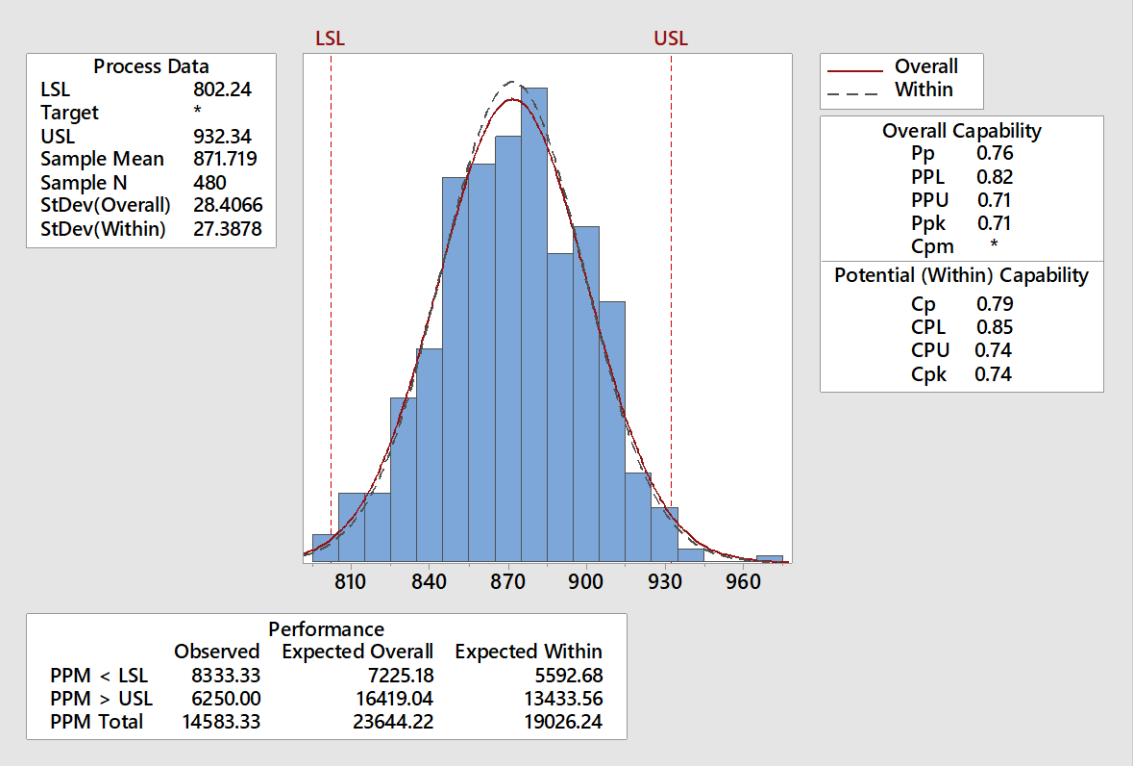


Figure 4-9 Process capability chart after remove sample 6

From Figure 4-9, it can be observed that Cpk has increased by 0.01 after removing sample 6, which is much lower than the benchmark (1.33). Cp (0.79) and Cpk (0.74) being approximately equal, suggested that process centre was

not a major contributor towards low Cpk. The analysis on Ppk provided a similar result.

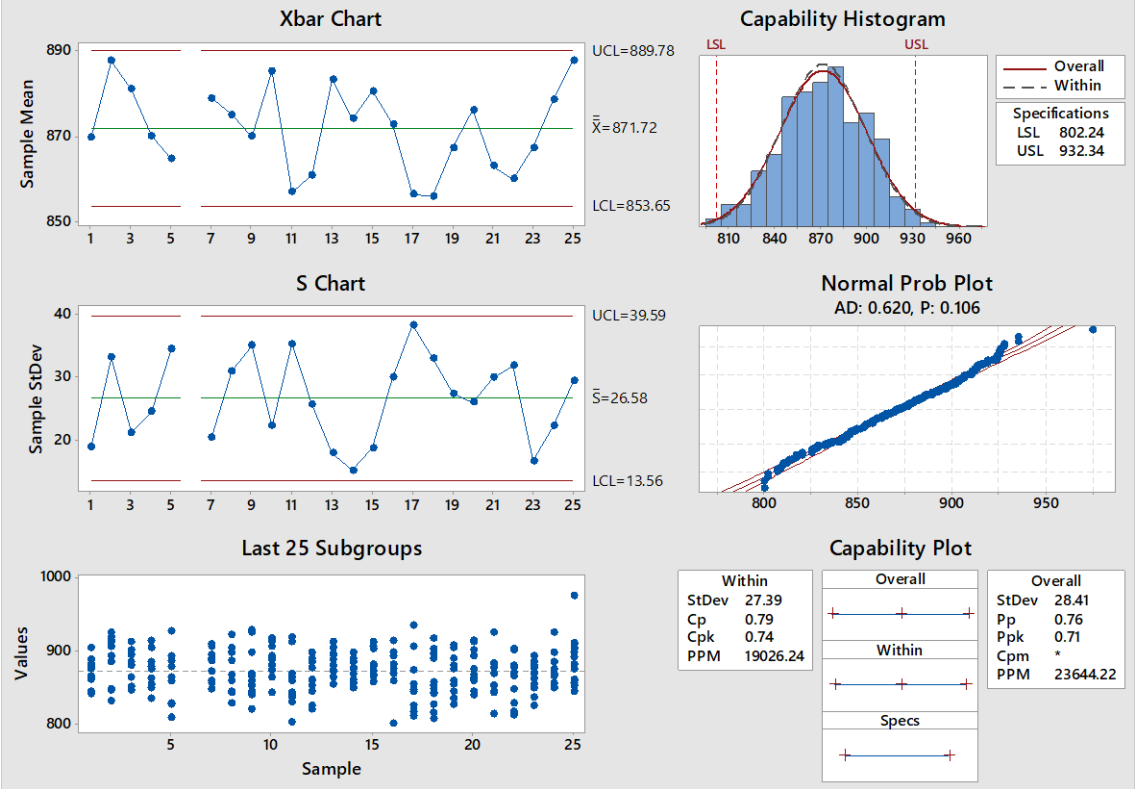


Figure 4-10 Process capability six-pack chart after removing sample 6

Figure 4-10 indicates that the process variation exists due to common causes only, which is not a surprise because the assignable cause (sample 6) has been removed from the data. Although the process is centred, low Cpk (and Ppk) suggested that it is crucial to reduce process variation. The team accepted this and agreed that the action drafted by them (the course of action listed in Section 4.4) can reduce the happening of special causes such as the one they encountered with sample 6.

The team understood that the right response to poor process capability caused by common variation was to reduce the common variation associated with the process. The team accepted that reducing the variation inherent in the capsule filling process is no trivial task as it might require a major redesign to the process/equipment; the team was also told that statistically designed experiments known as robust design experiments such as Taguchi methods are also at the disposal of the engineers as low cost solution that often works; in

robust designs fixing the parameters of the process to reduce common cause variation caused by uncontrollable factors remain the key (Roy, 2010; Summers, 2010; Taguchi, 1986). Luckily, in this instance, the active medicinal ingredient was Magnesium (Mg), for which a wide tolerance is quite acceptable for humans. Consequently, the quality improvement team decided that unless there is a strategic reason to do so, reducing common cause variation for the process under review is unwarranted, whatever Cpk and Ppk suggested.

4.6.3 Presenting the Findings to Top Management

The findings of the SPC implementation project were presented to the senior managers in a management review meeting. The researcher made the mistake of showing things that are important as well as unimportant to the management. One lifelong lesson that the researcher learned from this project is that all improvement suggestions must accompany cost of implementation and cost of maintenance estimates, if one is approaching the top management with improvement suggestions.

The researcher made the cardinal mistake of not being able to providing a benefit vs cost analysis of SPC implementation, but the management was very supportive, and they accepted the contribution made by the team in spite of few shortcomings, such as not considering cost aspect and failing to provide timelines for an SPC implementation project. In hindsight the researcher felt that the quality improvement team should have included a cost accountant. However, the quality assurance department opined that no additional training costs are involved, and if required, they can use SPC tools without any burden on direct and indirect costs.

The reader should note that strategic justification of SPC was not included in the scope of the project. However, the onus of explaining how SPC might relate to cost leadership and quality performance (e.g. reduced defective rates and customer complaints) remained with the researcher.

4.7 WHAT THE CASE STUDY PARTICIPANTS AND THE RESEARCHER LEARNED FROM THE PROJECT

The case study participants experienced the following benefits of SPC in a PCM environment:

1) Reduced giveaway and unnecessary rejections at the final inspection stage. The systematic and explanatory records, which can be shown to the customer as evidence of cGMP.

2) Improving the process: if the company is familiar with SPC techniques, they can approach the purchasing customer (i.e. the wholesalers and distributors) and show how capable they are. They can even tell the customer that their manufacturing process is so robust that they do not need such a wide tolerance. By showing that a producer is superior to competitors, both the producer and the purchasing customer can capitalise (e.g., charge a premium price for the product).

3) SPC is not a complicated thing for a person with a statistical thinking mindset. This is the reason why the quality assurance department opined that they could implement SPC tools that the researcher used with minimal incremental cost.

4) The staff buy-in for SPC tools was steady, but some limitations on the part of the researcher (for example language, culture, and inexperience at management level) meant that she could not sell what she led every effectively, particularly to the senior managers.[5] If the researcher were to brief senior staff again, she knows what information should have been provided (e.g. a cost benefit justification) and what information should not have been provided to senior managers (e.g. statistical analysis details).

5) There could be a potential (low to moderate) to resist implementing and sustaining SPC from the lower echelons of staff (some phrases used in

[5] The researcher lived in mainland China in her formative years, and English is her second language.

the conversations such as “if necessary”, “if available” suggested so), and this must be managed. The culture in the company is of “supportive” type, and because top managers are very competent in human relations, the researcher does not anticipate any significant resistance to change. Besides, activities such as measurement, testing, and calibration are at the very heart of chemistry in general and pharmaceutical industry in particular.

SPC has been implemented in different industries by a large number of researchers. Eissa and Hamed (2019) have implemented SPC to Pharmaceutical company, same as the researcher, they found the SPC tools has improved process visibility and understanding. The company gained many benefits from the implementation of SPC, and the system has significantly reduced process variation and improved cost-saving. One of the limitations of the study was that the researcher didn't put the cost into consideration. Hence the researcher was unable to provide the amount of cost saved after implementing SPC in the studied company.

Furthermore, Essia and Abid (2018) have noticed that SPC can be monitoring the overall manufacturing cycle performance of a product rather than reliance on product release specifications. After implementing SPC, the company became competitive, and customer satisfaction has increased (Psomas & Fotopoulos, 2010; Ra'bago-Remy, Padilla-Gasca, & Rangel-Peraza, 2014). There are some barriers that the researcher didn't experience during the study, for example:

- A systemic training was difficult for staff who is lack of statistical knowledge (Abtew, Kropi, Hong, & PU, 2018),
- The organisation has not entirely accepted the need for continuous improvement techniques (Hung & Sung, 2011),
- Lack of management participation (Hersleth & Bjerke, 2001) and employee empowerment (Hersleth & Bjerke, 2001).

4.8 DISCUSSING THE FINDINGS IN THE LIGHT OF EXTANT LITERATURE

SPC has been implemented in different industries by a large number of researchers. Like the researcher, Eissa and Hamed (2019) implemented SPC in a Pharmaceutical company. They found that SPC tools improve process visibility and understanding. The company gained several benefits by implementing SPC including reduced process variation and improved cost-savings. As mentioned already, one of the limitations of the researcher's study was not considering the cost aspect relative to benefits. Hence, unlike Eissa and Hamed (2019), the researcher was unable to provide the amount of cost saved after implementing SPC in her case study company.

Essia and Abid (2018) showed that SPC can be used to monitoring the overall manufacturing cycle performance of a product as opposed to reliance on product release specifications. According to Essia and Abid (2018), after implementing SPC, the company became competitive, and customer satisfaction has increased. Similar claims have been made by Psomas and Fotopoulos, 2010; Ra'bago-Remy et al. (2014).

Unlike the following studies, the researcher's study did not surface significant barriers to SPC implementation:

- Abtew et al. (2018) found that systemic training was difficult for staff as they lacked statistical knowledge.
- Hung and Sung (2011) found that their organisation did not entirely accept the need for applying continuous improvement techniques.
- Hersleth and Bjerke (2001) found lack of management participation and employee empowerment in quality improvement interventions.

The discrepancy between the above findings and the researcher's finding may be attributed to any one or a combination of the following: (a) a more favourable organisational culture in the researcher's case study organisation, (b) since the researcher was a young employee, the quality improvement team and the leadership may not have wanted to dampen the researcher's enthusiasm, (c) the

researcher may have subconsciously picked people with whom she is comfortable in working with.

4.9 SUMMARISING THE FINDINGS TO ANSWER RQ1, RQ2 AND RQ3

The data collected from the SPC case study enabled the researcher to answer RQ1, RQ3, and RQ2 (partially). RQ2 and RQ4 will be fully answered in Chapter 5. The researcher was able to achieve the following from the SPC mini journey.

- The researcher was able to confirm that the Six-step SPC implementation technique (Berk & Berk, 2000) can be used as a framework for quality control and quality improvement of a PCM company. The key is selecting the right quality characteristic for process monitoring and improvement. SPC tools of course can be used at different stages of implementation. For example, in Step 3 of 6, the Ishikawa diagram is usually needed (as in this project) for root cause analysis of a problem (in this project, excessive weight variation, which in the end turned out to be acceptable after all, given the very high tolerance allowed). RQ1 asks “what constitutes an acceptable SPC programme for a typical PCM company?” and this was answered via the SPC mini-journey embarked by the researcher and her team; consequently, the researcher maintains that her first research objective has been achieved.

- The SPC mini-journey confirmed that supportive management, correct SPC tools usage, operator and management training, process knowledge, technical support, awareness and above all willingness to change are the enablers for this SPC implementation. This partially answers RQ2.

- The SPC mini-journey confirmed that SPC is a suitable technique for identifying and understanding variation during the process. After pointing out and removing the special cause of variation, the process capability improved, albeit slightly. The team realised that the condition would have been much worse if the operator was not been able to detect the

assignable cause in time and pull back the process into control by taking remedial action. The team also learnt that reduction of common cause variation in the process (unassignable variation or variation that is inherent in a process) is a more challenging proposition but there are ways and means of tackling this such as PDSA lead continuous improvement (including the application of the cause and effect diagram as an SPC tool), statistically designed process improvement experiments such as robust designs (e.g. Taguchi method) when there is an economic/strategic advantage in doing so (i.e. reduce common cause variation). In the main, it can be concluded that SPC tools help a great deal in in solving critical-to-quality problems but economic and strategic justification of SPC implementation remains important; the study also found that there is a natural affinity between measurement and analysis led pharmaceutical manufacturing and SPC led quality control and improvement. This answers RQ3 to achieve the third research objective.

4.10 CHAPTER CONCLUSION

The case study was designed to demonstrate the simplicity of the application of SPC tools as well as to observe how operations staff and the leadership would react to SPC implementation in a PCM context. The PCM company is not presently applying any of the major SPC tools such as variable control charts or process capacity histograms. It was hoped that successful outcomes achieved through the researcher's SPC project, and this thesis (or an executive report generated from the thesis) would increase staff buy-in, regardless of their specialisation. Staff buy-in within and outside the quality control department (especially the manufacturing floor and liner managers' acceptance) is necessary to sustain SPC.

The researcher demonstrated that by establishing and using SPC, the operations department could provide confidence to their internal customers (e.g. sales and marketing) and external customers that they are unlikely to departure from the specification and thereby reduce the likelihood of litigation (for false declarations)

under the cGMP. SPC can also make the manufacturing process honest because SPC stars by identifying the quality characteristics of the product (or the process that manufactures the product) and assessing the risk of nonconformance.

Apart from altering the operator to the intrusion of a potential special (assignable) cause(s) of uncontrolled variation (e.g. machine malfunction), the other main function of these charts was the prediction. Control charts can be used to reveal trends in subsequent samples, which alert the controller to potential violations, and non-random variations (e.g. trends due to tool wear, machine wear). By definition, special cause variation is correctable — earlier the correction, the better. Special cause variation is correctable because special cause variation occurs due to faults such as raw material quality issues, machine malfunction, machine or tool wear, shift-to-shift variation and the like (Summers, 2010). Common cause variation is different because common cause variation is random and unavoidable, unless a major intervention such as process re-design or experiment-lead parameter adjustment has been implemented.

Above said, by using control charts, acceptable limits can be established on common causes, and special causes can be identified for corrective action. Once the stability has been established via control charts (i.e., the standard deviation of the process is reliable for prediction purposes), the manufacturing and quality control staff can answer the most important question: “is the process capable of meeting the specification imposed upon it by the customers?”. This was the very reason why process capability analysis became the natural end-result of statistical process control. The staff who participated in the project learnt all this by doing things!

The next chapter presented the results of the survey data and an accompanying discussion.

Chapter 5 SURVEY DATA ANALYSIS RESULTS AND DISCUSSION

5.1 INTRODUCTION

The survey questionnaire was administered upon the staff of the PCM company to collect data to test statistical hypotheses and to make inferences related to research questions, more specifically RQ2 and RQ4. In this chapter, the researcher analyses the survey data and interprets the results from a theoretical and practical perspective, leading to a discussion on results. The data analysis contains two main sections: a section on descriptive statistics (Section 5.2) and a section on inferential statistics (Section 5.5), preceded by two sections (Section 5.3 and 5.4) concerning reliability and validly of the survey and the measurement scales. Coming back to the inferential statistics section, as the name implies, Section 5.5 was used for making statistical and practical inferences (projections). As part of the discussion of results from a practical perspective (subsections of Section 5.5), some analytically generalisable recommendations have been provided to implement SPC successfully in the SPC company. However, the main aim of this chapter, as mentioned at the very beginning of this chapter, is to answer RQ2 and RQ4 more fully (Section 5.6), using the findings of this chapter.

5.2 DESCRIPTIVE STATISTICS BASED ON SURVEY RESPONSES AND THE ADEQUACY OF SAMPLE SIZE

As mentioned earlier, upon pilot testing, 150 finalised questionnaires were distributed to employees who work in the Production department (N = 128), Quality Control department (N = 12), and Quality Assurance department (N = 10). Out of the 150 questionnaires dispatched, 76 were returned with responses, resulting in a raw response rate of 50.7%. All the responses received were usable, as there were no large chunks of missing data or unusual patterns of responses (e.g. 7s for all the Likert-style survey items). The question is whether or not the sample size of 76 is adequate for the data analysis.

In one of the most cited articles in statistics for social research, Cohen (1992) provided a scientific basis and guidance to determine the minimum sample size required for popular statistical techniques (ANOVA and multiple regression included), based on power analysis. In the PLS approach to structural equation modelling, being a piece-meal regression method, the minimum sample size is governed by the most complex structural relationship — the predictor-response relationship that has the most number of predictors (Chin, 1999; Hair et al., 2014). In the researcher's two structural models (see Figures 5.8 and 5.10) the most complex structural relationship(s) has only two predictors (incoming arrows), and given the size of the anticipated relationship (R^2 or Cohen's f^2), given the fact that the most complex the predictor-response has two predictors, according to Cohen's power analysis calculations, the minimum size is 481 if the anticipated Cohen's f^2 is 0.02 (this translates to an R^2 of 2% and Cohen calls this a small effect). If the anticipated Cohen's f^2 is 0.15 (this translates to an R^2 of 13% and Cohen calls this a medium effect), the minimum sample size lowers to 67. On the other hand, if the anticipated Cohen's f^2 is 0.35 (this translates to an R^2 of 26% and Cohen calls this a large effect) the minimum sample size lowers to 30 (see Cohen, 1992, pp. 157-158). Anticipating R^2 values around 26% (0.26) is realistic (judging by past studies) but one can argue that the researcher has been too optimistic. Consequently, an anticipated Cohen f^2 of 0.15 (anticipated R^2 = 13%) was chosen which means that any sample equal or greater than 67 would suffice for the study. Thus, the researcher's sample size is adequate for her key analyses. [6]

5.2.1 Demographic Information

5.2.1.1 Age Group

Figure 5-1 suggests that majority of survey participants were in the 22 - 25 age group (30%). In addition, 24% were in the 26 - 30 age group (details in Figure 5-1). This age profile tallies with the apparent age profile of the staff in the three departments in which the survey was administered, implying no apparent non-

[6] The following URL may be used for verification: https://www.danielsoper.com/statcalc/calculator.aspx?id=1

response bias. Records on staff, including the age of the employees are treated by the company as part of personal information, and it was inappropriate on the part of the researcher to request the human resource manager to disclose the age of the staff!

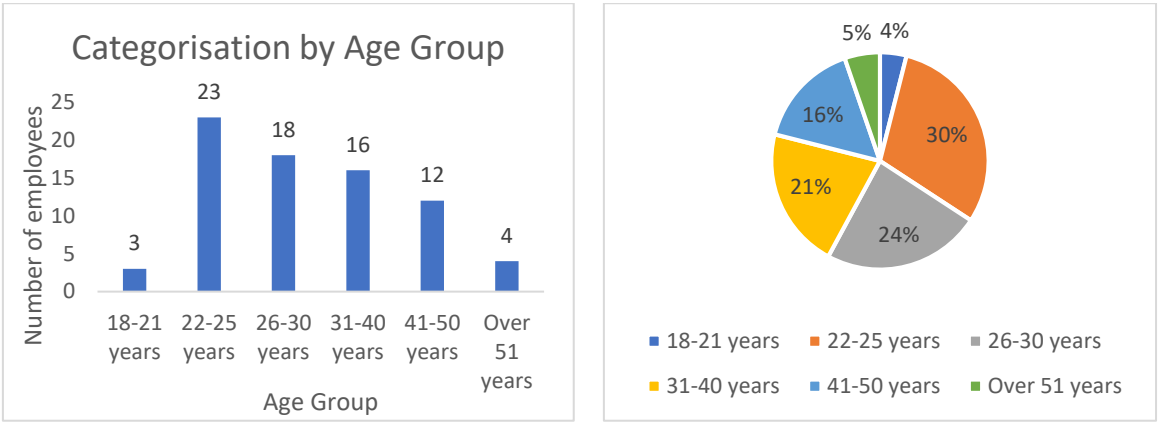


Figure 5-1 Age distribution of the respondents

Work Experience in the Company

Figure 5-2 indicates that approximately half of the participants have worked in the company for more than two years (39 out of 76, which is 51%). However, 27 out of 76 (36%) of the participants have less than a year's work experience. For most jobs, staff skills are transferable, and hence a relatively inexperienced workforce would unlikely be an issue (surely, there is no perception in the company that their workforce is inexperienced).

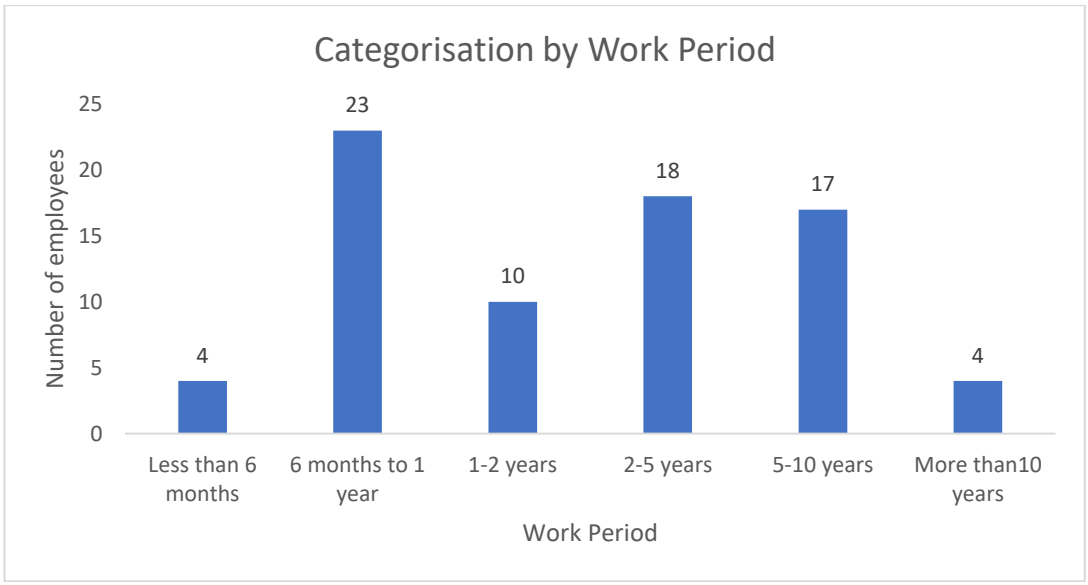


Figure 5-2 Work period distribution of the respondents

5.2.1.2 Education

Table 5-3 indicates that most of the participants (73 out of 76, which is 96%) have high school and higher educational achievements. Furthermore, 53 out of 76 (70%) participants have Bachelor and higher education levels (Table 5-3). Additionally, the proportions of education levels found through this survey seemed to tally with the apparent educational level the company, based on verbal conversations the researcher had with the human resource manager; as mentioned earlier, official personnel records were not solicited from the human resource manager. The aforementioned tallying based on education level suggested that as far as regular staff is concerned (i.e., all but holiday visa holders), three is no apparent non-response bias associated with the survey.

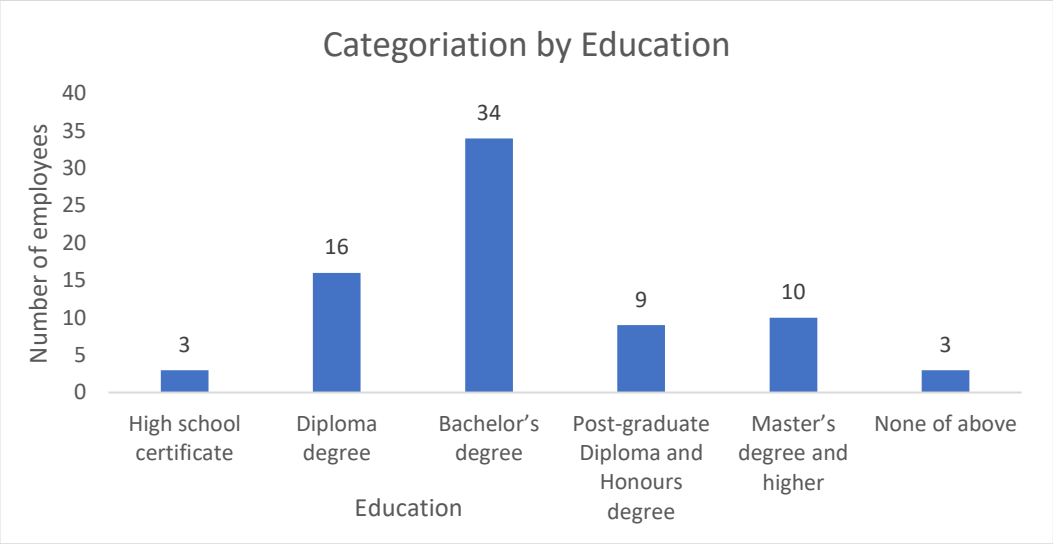


Figure 5-3 Education level distribution of the respondents

5.2.1.3 Employment Category

Figure 5-4 indicates that approximately half (37 out of 76, which is 49%) of the participants represent frontline workers. Among staff who play managerial roles, most are coordinators, Quality Controllers such as supervisors, and staff from the Quality Assurance Department playing managerial roles.

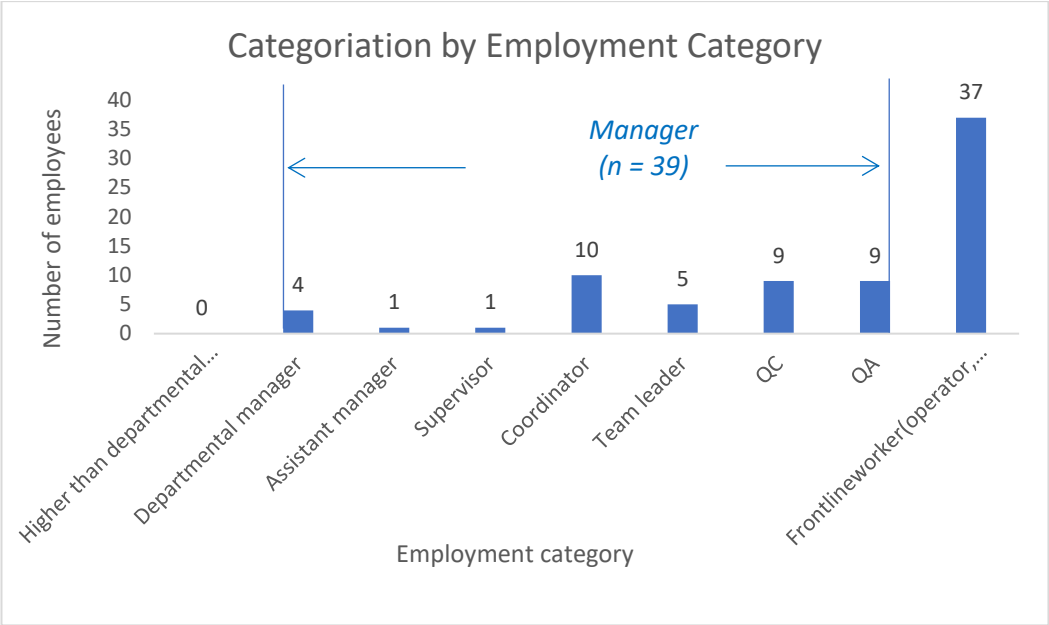


Figure 5-4 Employment category distribution of the respondents

5.2.1.4 Visa type

Figure 5-5 shows that most (85%) of the participants are NZ citizens or residents. 11% of the participants have a working visa, and only 4% of the participants have a working holiday visa.[7] Fewer number of responses from working holiday visa holders lowers the statistical power of any hypothesis that involves visa type as a factor, but this could also be a blessing in disguise because over representation of working holiday visa holders could mis-represent the quality improvement climate of the organisation.

[7] As mentioned earlier, working visa holders are allowed to have only 3-month contracts, as required by law.

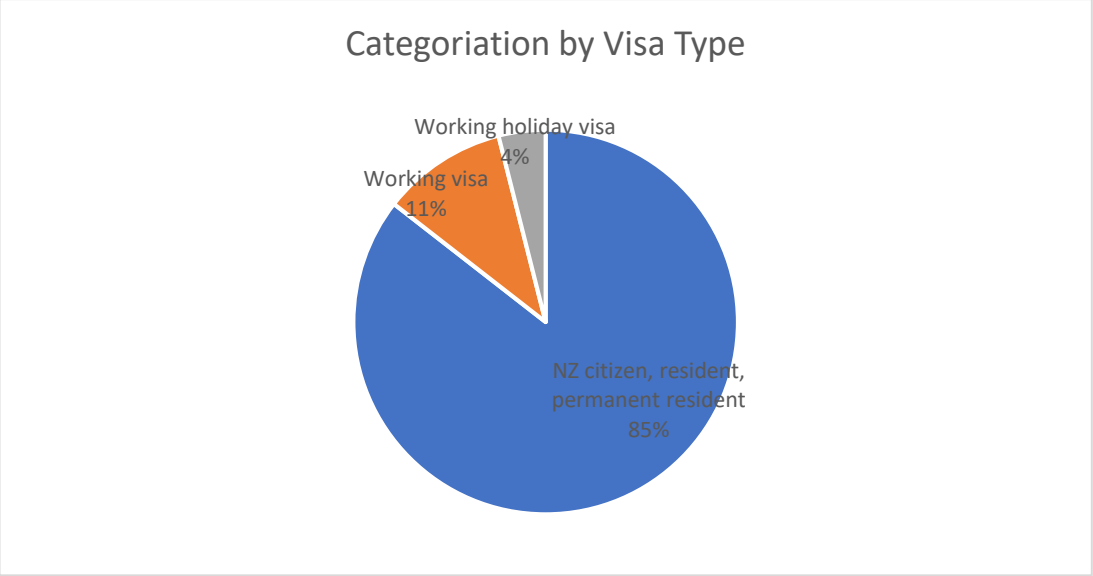


Figure 5-5 Visa type distribution of the respondents

5.3 PRINCIPAL COMPONENTS ANALYSIS (PCA) TO PERFORM THE SINGLE FACTOR TEST

A self-reported (also called self-administered) questionnaire, meaning a questionnaire designed to be answered by a respondent him/herself without any intervention or prompting by a researcher, is particularly susceptible to biases for several reasons, including lack of interest, lack of knowledge to answer the questions. This could lead to so-called satisfying responses (Donaldson & Grant-Vallone, 2002; MacKenzie & Podsakoff, 2012; Podsakoff & Organ, 1986). In such instances, variances of constructs and covariances between constructs are significantly affected (biased) due to flaws in the questionnaire (e.g. wrong wording) or the way the questionnaire has been administered (MacKenzie & Podsakoff, 2012). Bias creeping in this fashion to data is known as common method bias (CMB). CMB causes false positive or false negative errors (Chang, Witteloostuijin, & Eden, 2010).

Harman's single factor test (Harman, 1976) was used to demonstrate the absence of CMB in the responses. Within an exploratory factor analysis (EFA) framework, if a single factor (component if principal components analysis is used in EFA) accounts for majority of the covariance among measures in a

questionnaire, according to Harman's single factor test, the responses are treated as being suspect (biased). Consequently, if one needs to demonstrate that the responses are free from substantial CMB, they need to show that multiple factors emerge in EFA (i.e. multiple factors returning Eigenvalues in excess of 1.0) and that the first factor does not extract more than 50% of the covariance among measures. The researcher used the PCA method to determine how many components are required to extract the bulk of the variability of the 46 questionnaire items (see Table 5-1 to know to which construct each questionnaire item/indicator belongs).

Figure 5-6 (the scree plot) shows that PCA conducted via Minitab 18 extracted as many as nine factors (Eigenvalues > 1.0) and that the first component extracts 47.5% of the total variance of the measures (21.8515 x 100 / 46 = 47.5%). Thus, the scree plot indicates that more than one factor is accountable for majority of the covariance among measures and that the data are free from substantial CMB.

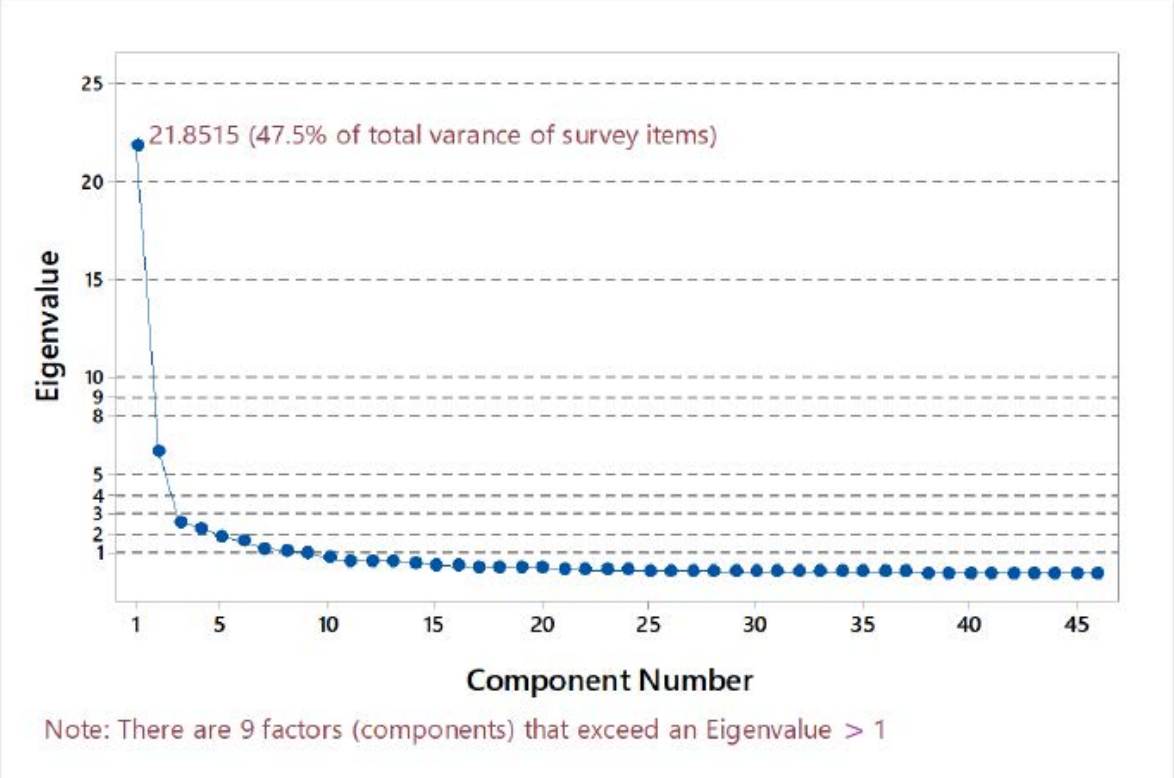


Figure 5-6 Scree plot of the 46 survey items

Table 5-1 Indicators of Latent Variables

Latent variable name	Indicators
Information and Analysis	INF1, INF2, INF3, INF4, INF5, and INF6
Top Management Commitment	MAG1, MAG2, MAG3, MAG4, and MAG5
Customer Focus	CUF1, CUF2, CUF3, CUF4, CUF5, CUF6, CUF7, and CUF8
Human Resource Management	HRM1, HRM2, HRM3, HRM4, HRM5, HRM6, and FRM7
Benchmarking	BEM1, BEM2, BEM3, and BEM4
Quality Assurance Activities	QAA1, QAA2, QAA3, QAA4, and QAA5
Process Management	PM1, PM2, PM3, PM4, PM5, and PM6
Quality Performance	QP1, QP2, QP3, QP4, and QP5

5.4 TESTING THE RELIABILITY AND VALIDITY OF THEORETICAL CONSTRUCTS

All the hypotheses that underpin this study involved latent variables — that is, variables that are not directly observable but are indirectly observable as different manifestations. In this study, those different manifestations are the questionnaire items theoretically assigned to each latent variable (Table 5-1). In latent variable methods, it is necessary to establish the reliability of the measurement scales of each theoretical construct as well as the validity of the scales (Hair et al., 2014; Straub, Boudreau, & Gefen, 2004).

Since the researcher used the PLS approach, the validity of the constructs (scales) was demonstrated by fulfilling two conditions. Firstly, it must be shown that measurement items (in this study questionnaire items) assigned to a construct do strongly correlate with the construct (i.e. strong factor loadings need to be shown). This is known as *convergent validity* (Hair et al., 2014; Straub et al., 2004). Secondly, it must be shown that measurement items that are not assigned to a construct correlate (cross-loads) much less with the construct than the correlations theoretically assigned measures have with the construct. This is known as *discriminant validity* (Hair et al., 2014; Straub et al., 2004). To test the

convergent and discriminant validity in PLS mode (the mode used by the researcher as justified in Chapter 3), the data analyst needs to specify their measurement model (i.e. which measures were linked to which construct) and the hypothesised structural model together (Figure 5-7) and estimate the required correlations and other parameters.

For convergent validity, each measurement item must ideally show a loading greater than 0.7. In addition, the average variance extracted by measures of a construct relative to measurement error (this ratio was abbreviated as AVE in statistics) must be 0.50 or higher (Chin, 1999; Hair et al., 2014; Straub et al., 2004). Finally, it must be shown that measures of a construct are sufficiently related to one another to be reliable (Straub et al., 2004). This form of reliability is known as internal consistency reliability (Nunnally & Bernstein, 1994).

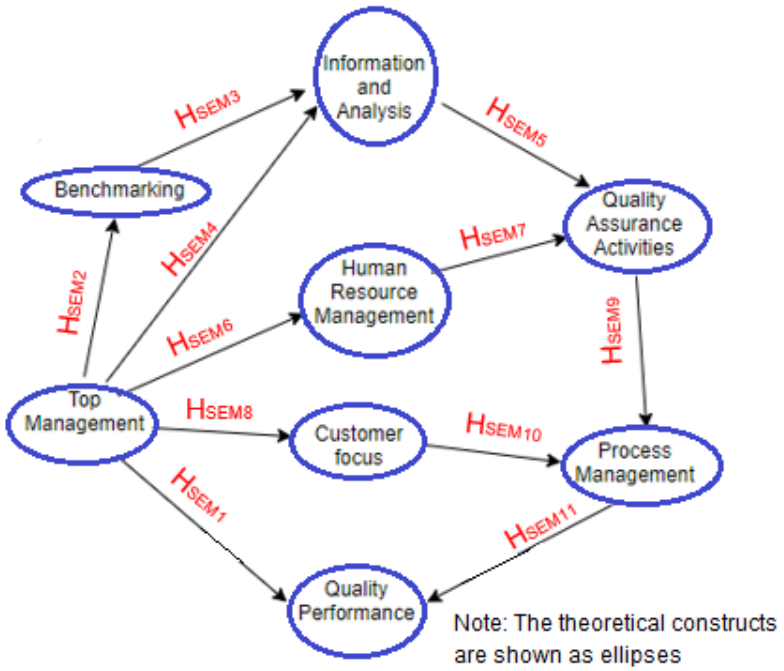


Figure 5-7 Relationship among the hypotheses on the TQM approach

5.4.1 Testing for Convergent Validity

SmartPLS analysis showed that six out of 46 questionnaire items fail to meet convergent validity due to low loadings (i.e., factor loadings < 0.700). These questionnaire items are listed in Table 5-2. The six low-loading questionnaire items mean that respondents do not feel that the measurement sub-domains

covered by these survey items are existing in the PCM company, in the wider scheme of things (i.e. relative to measurement sub-domains covered in other measurement items). A discussion on this finding is covered later.

Table 5-2 Questionnaire Items That Fail to Meet Convergent Validity

Latent Variable	**Deleted question number**	**Loading**	**Deleted questions**
Top Management Commitment	MAG5 (Q11)	0.459	Quality issues related to our products and services attract the attention of our top managers.
Customer Focus	CUF5 (Q16)	0.481	We use information collected from our customers (e.g. customer needs, feedback on current products) in designing new products and services.
	CUF6 (Q17)	0.050	Our top management frequently contact the customers.
Human Resource Management	HRM1 (Q20)	0.320	Employee involvement programme are implemented in our company.
	HRM3 (Q22)	0.460	Employees in our company hold responsibility for the output they provide towards the processes.
Process Management	PM2 (Q37)	0.532	Our company provides product specifications to employees engaged in quality control activities.

The PLS analysis was repeated via SmartPLS after removing the six offending qursionnaire items (Table 5-3). The final measurement model and the strcuctural model is shown in Figure 5-8. The re-analysis confirmed that the AVE of each constrcut exceeds 0.50, which re-affirms convergent validity.

Table 5-3 AVE and Reliability Coefficients of the Constructs

Construct (Latent Variable)	Average Variance Extracted (AVE)	Scale Reliability Coefficients	
		Cronbach's Alpha	Composite Reliability
Top Management Commitment	0.854	0.956	0.970
Customer Focus	0.615	0.902	0.924
Benchmarking	0.689	0.891	0.927

Information and Analysis	0.557	0.877	0.906
Quality Assurance Activities	0.743	0.933	0.952
Human Resource Management	0.587	0.859	0.905
Process Management	0.572	0.848	0.903
Quality Performance	0.576	0.850	0.899
Note: Minitab was used to obtain Cronbach's Alpha as there is a known issue with SmartPLS in under-estimating Cronbach's Alpha (Hair et al., 2014).			

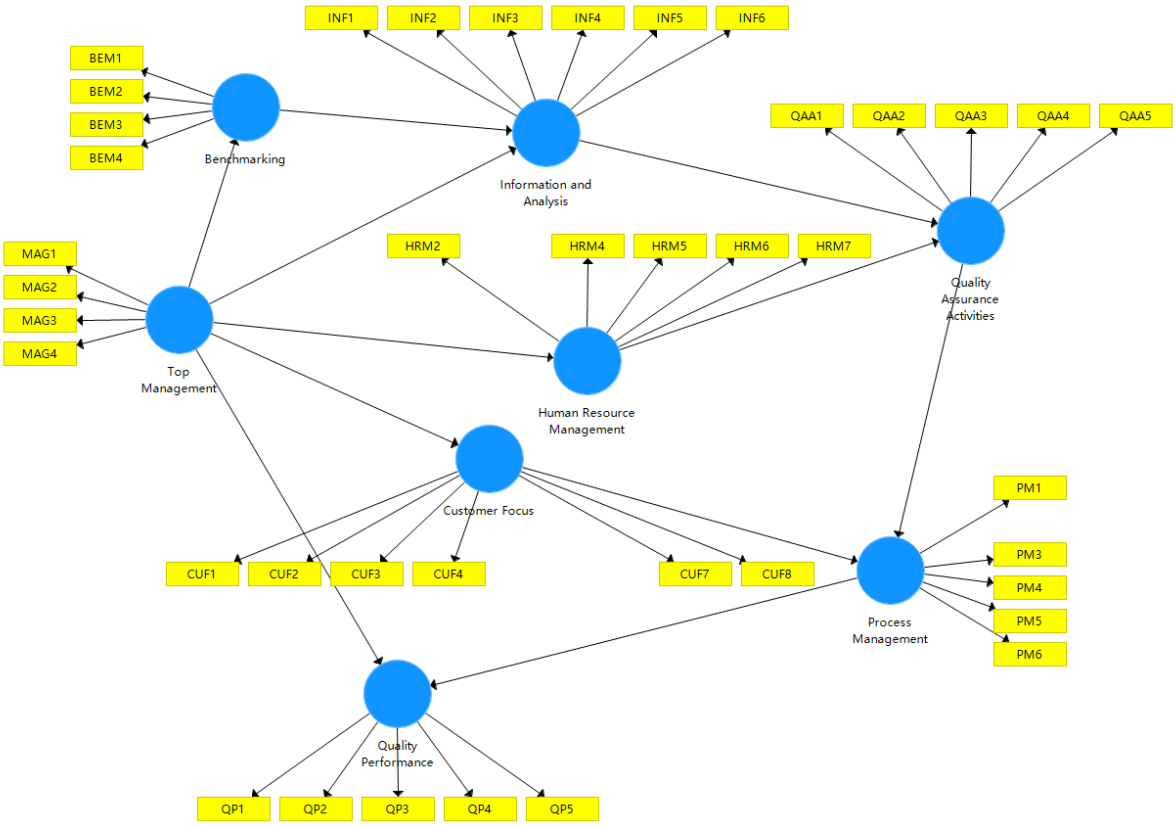


Figure 5-8 The final measurement and structural models

5.4.2 Testing for Discriminant Validity

The discriminant validity of scales can be established in three ways. The first way is to examine cross-loadings relative to loadings and show that loadings are greater than cross-loadings. This method is now obsolete because this method is now deemed not stringent enough to pass scales for theory testing purposes (Henseler, Ringle & Sarstedt, 2015). The second way, which is slightly more

stringent (still considered old-fashioned) than the first way is to show that a construct correlates more strongly with its assigned measures — as indicated by the square root of the AVE — than other constructs (Chin, 1999; Hair et al., 2014). This criterion is known as the Fornell-Larcker criterion (Fornell & Larcker, 1981). The third method, which is the stringent of the three tests, considers Heterotrait-Monotrait (HTMT) ratios of correlations involving the measures. For clear discriminant validity, this criterion requires all HTMT ratios of correlations being 0.90 or less (for details see Henseler at al., 2015). HTMT ratios of correlations in excess of 0.90 but less than 1.0 are questionable, while HTMT Ratios of correlations in excess of 1.00 are unacceptable (Henseler et al., 2015).

The HTMT ratios shown in Table 5-4 show that there are some issues with discriminant validity. Such issues often occur due to overlapping conceptual domains (Henseler et al., 2015), which is understandable in the context of this research because there are several overlapping domains (e.g., between hard factors of TQM/SPC). The HTMT ratios in Table 5-4 suggest that the greatest overlap between constructs is between benchmarking and process management, and this is understandable. Removing some survey items to improve HTMT ratios was not considered because the researcher used a survey instrument that has been validated before. The overall conclusion on discriminant validity is that scales may raise few doubts about discriminant validity but are acceptable for the purpose of proceeding with the remainder of the analysis.

Table 5-4 HTMT Ratios of Correlations

	Benchmarking	Customer Focus	Human Resource Management	Information & Analysis	Information & Analysis	Qual Assurance Activities	Quality Performance	Top Management
Benchmarking								
Customer Focus	0.861							
Human Resource Management	0.828	0.863						
Information & Analysis	0.808	0.889	0.899					
Process Management	0.945	0.878	0.761	0.868				
Qual Assurance Activities	0.865	0.552	0.666	0.687	0.866			
Quality Performance	0.762	0.732	0.819	0.912	0.845	0.630		
Top Management Commitment	0.684	0.828	0.840	0.901	0.797	0.444	0.792	

Note:

HTMT ratios $\leq$ 0.85 (figures in green font) are well clear of issues. HTMT ratios in black font are ratios $\leq$ 0.90 but greater than 0.85; these are still acceptable, but the ones in red are HTMT ratios > 0.90, which are flagged as questionable (these being < 1.00 provide some solace).

5.4.3 Testing Internal Constancy Reliability

SamrtPLS uses two internal consistency reliability coefficients: Cronbach's alpha (Cronbach & Meehl, 1955) and composite reliability coefficient (Werts, Linn, & Jöreskog, 1974). For acceptable levels of reliability for basic research, the values of these coefficients need to be equal or greater than 0.80, although values between 0.70 and 0.80 are acceptable for new scales designed for basic research (Nunnally,1978). As shown in Table 5-3, all reliability coefficients of the scales used in this study easily exceed the prescribed cut-off of 0.80 for an acceptable level of reliability. The conclusion is that the scales are reliable.

5.5 HYPOTHESIS TEST RESULTS

Having demonstrated the theoretical validity of the TQM/SPC constructs, the next step is to show and review hypothesis test results involving the latent variables.

5.5.1 Test Results on H1

H1: In a PCM environment, frontline workers have less access to quality-related data than their managers.

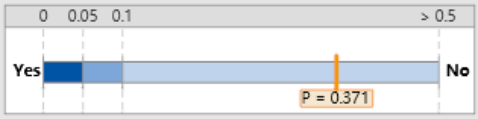
To make such a comparison, the two-sample t-test was performed in Minitab. The score of quality-related data were taken as the average score from the six indicators of Information and Analysis (i.e. the average of INF1 score through to INF6 score). Table 5-5 depicts the two-sample t-test results. In the analysis, the two-level factor "Position" has been used as the independent variable. One level of the factor represented the sample of staff in managerial roles while the other level represented the sample of staff in front-line worker roles (also see Figure 5-4).

Table 5-5 depicts the test results of the two-sample t-test. The mean scores of both groups hover around the 5.0 mark (also see Figure 5-9). The mean score of 5.0 translates to “somewhat agree”, which means that both groups, on average, somewhat agree that they have access to data and information. More importantly there is not enough evidence at 5% significance level (95% Confidence Interval (CI)) to conclude the mean of Frontline workers is less than Manager. Thus, data fails to support H1. From a practical perspective, this means that based on the data collected from the PCA, there is no evidence to support the notion that front-line workers are starved of data and information required for SPC related decision making.

Table 5-5 Two-Sample T-Test Results to Test H1

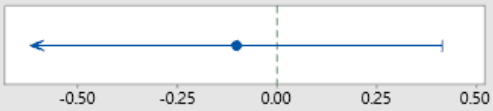
2-Sample t Test for Avearge by Position
Summary Report

Mean Test
Is Frontline less than Manager?

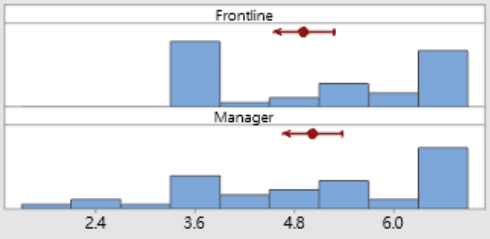


The mean of Frontline is not significantly less than the mean of Manager (p > 0.05).

95% Upper Bound for the Difference
Is the entire interval below zero?



Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Frontline	Manager
Sample size	37	39
Mean	4.9099	5.0128
95% Upper bound	5.285	5.3794
Standard deviation	1.3498	1.3580

Difference Between Samples

Statistics	*Difference
Difference	-0.10291
95% Upper bound	0.41469

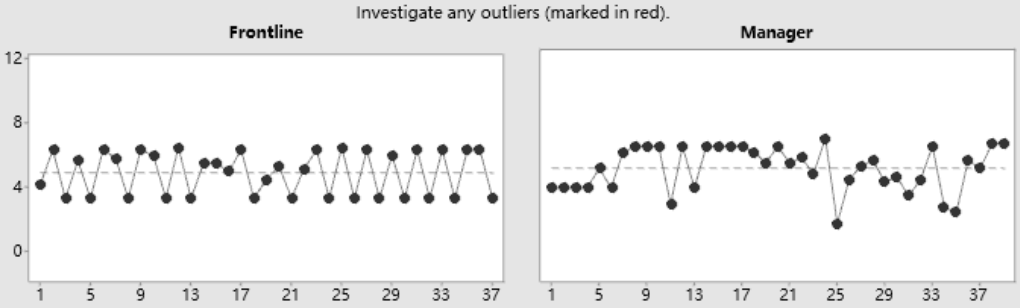
*Difference = Frontline - Manager

Comments

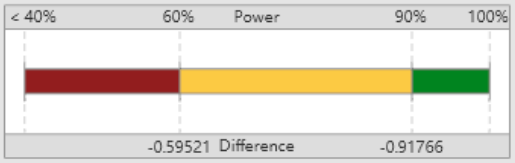
- Test: There is not enough evidence to conclude that the mean of Frontline is less than Manager at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is less than 0.41469.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

2-Sample t Test for Avearge by Position
Diagnostic Report

Data in Worksheet Order
Investigate any outliers (marked in red).



What is the chance of detecting a difference?



For α = 0.05 and sample sizes = 37, 39:
If the true mean of Frontline were 0.59521 less than Manager, you would have a 60% chance of detecting the difference. If Frontline were 0.91766 less than Manager, you would have a 90% chance.

What difference can you detect with your sample sizes of 37 and 39?

Difference	Power
-0.59521	60%
-0.68021	70%
-0.77969	80%
-0.91766	90%

Observed difference = -0.10291

Power is a function of the sample sizes and the standard deviations. To detect smaller differences, consider increasing the sample sizes.

2-Sample t Test for Avearge by Position
Report Card

Check	Status	Description
Unusual Data	✓	There are no unusual data points. Unusual data can have a strong influence on the results.
Normality	✓	Because both sample sizes are at least 15, normality is not an issue. The test is accurate with nonnormal data when the sample sizes are large enough.
Sample Size	i	Your data does not provide sufficient evidence to conclude that the mean of Frontline is less than Manager. This may result from having sample sizes that are too small. Based on your sample sizes, standard deviations, and α, you would have a 90% chance of detecting a difference of -0.91766. To determine how large your samples need to be to detect a difference that has practical implications, repeat the analysis and enter a value for the difference.
Equal Variance	i	Minitab' s Assistant uses Welch's method, which does not assume or require that the two samples have equal variances. Research shows that the test performs well with unequal variances, even when the sample sizes are not equal.

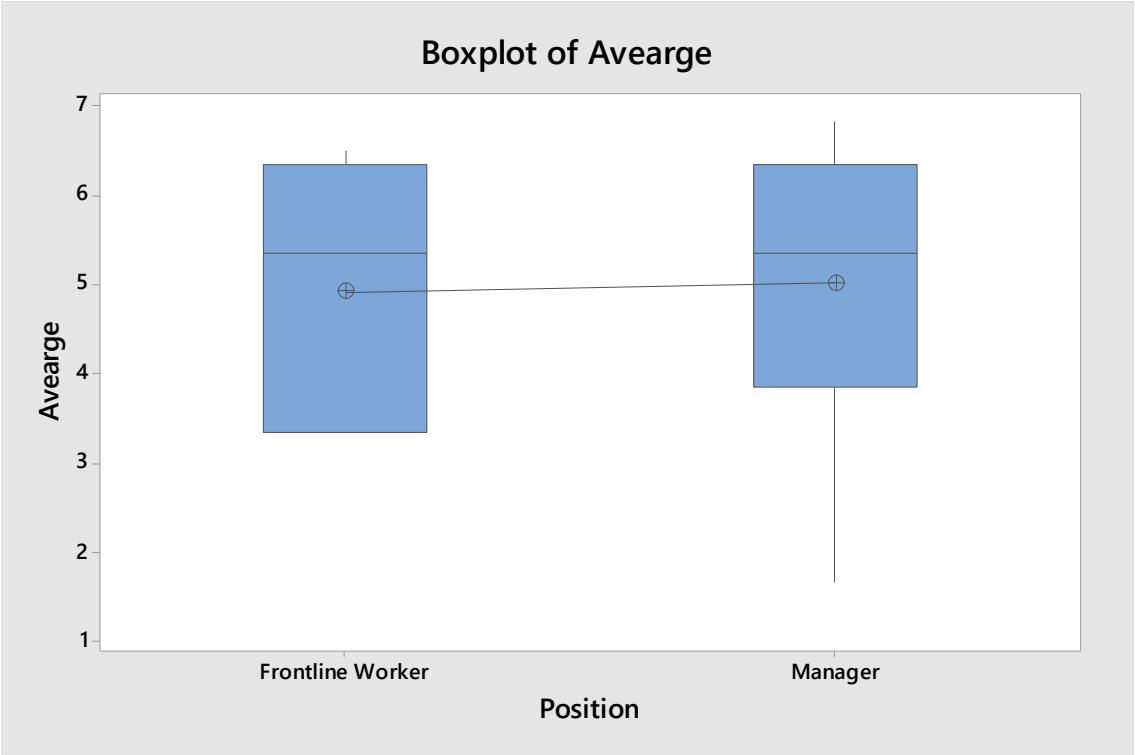


Figure 5-9 Box plot of access level of quality-related data among frontline workers and managers

It was shown earlier that only 4% of the participants are holding working holiday visas, which is seemingly an under-representation of working-holiday visa holders of the PCM company to the best of researcher's experience. This may cause an upward biasing of the mean score of Frontline worker group, which could contribute towards failing to support H1. It could be that because working holiday visa holders have a short working period (3 months) in the company, most of them may have opted not to respond to survey questionnaire; if this was the case, that is something beyond the control of the researcher.

5.5.2 Test Results of the Hypotheses of the Researcher's Path Model

Like in any regression analysis, in path analysis, not only the model parameters need to be estimated (e.g., size of the structural regression coefficients) but also their statistical significance. Since PLS is not a parametric approach, the statistical significance of the parameters is obtained via a non-parametric method such as jackknife or bootstrapping; both methods involve automatic resampling

(for details see Efron, 1979). SmartPLS *full bootstrapping* option was used to generate the critical ratios (t-values) and p values of the parameters.

Results of the path analysis of the TQM/SPC theory are shown in Table 5-6. Data support all hypotheses that constitute the researcher's theory on TQM/SPC, although H_{SEM7} is significant only at a 10% level (i.e. 90% CI). The results clearly indicate that Top Management Commitment not only drives the system via Benchmarking, Information and Analysis, Human Resource Management, and Customer Focus to achieve Quality Performance, but also, Top Management Commitment directly influences Quality Performance (H_{SEM1} was supported).

Table 5-6 Path Coefficients and T-values for Each Hypothesis in the TQM Theory

Hypothesis Label	**Hypothesised path**	**β**	**t-value**	**Result**
H_{SEM1}	Top Management Commitment → Quality Performance	0.584	4.993	Significant at 95%CI
H_{SEM2}	Top Management Commitment → Benchmarking	0.641	10.148	Significant at 95%CI
H_{SEM3}	Benchmarking→ Information and Analysis	0.297	3.629	Significant at 95%CI
H_{SEM4}	Top Management Commitment →Information and Analysis	0.650	9.696	Significant at 95%CI
H_{SEM5}	Information and Analysis→ Quality Assurance Activities	0.339	1.983	Significant at 95%CI
H_{SEM6}	Top Management Commitment → Human Resource Management	0.798	20.864	Significant at 95%CI
H_{SEM7}	Human Resource Management Commitment → Quality Assurance Activities	0.318	1.884	Significant at 90%CI
H_{SEM8}	Top Management Commitment → Customer Focus	0.812	17.327	Significant at 95%CI
H_{SEM9}	Quality Assurance Activities → Process Management	0.515	6.202	Significant at 95%CI

Hypothesis Label	Hypothesised path	β	t-value	Result
H_{SEM10}	Customer Focus→ Process Management	0.526	7.686	Significant with 95%CI
H_{SEM11}	Process Management→ Quality Performance	0.306	2.248	Significant with 95%CI

Most prior empirical studies that attempted to explanation of how critical success factors of TQM cause results (e.g., Bou-Llusar et al., 2009; Flynn & Saladin, 2001; Jayamaha, Grigg, & Mann, 2008; Mai, Ford, & Evans, 2018; Peng & Prybutok, 2015) fail to support evidence to support the hypothesis that Leadership directly affects results. While some studies showed a direct effect of Leadership on results (e.g. Badri et al., 2006; He, Hill, Wang, & Yue, 2011), these studies did not show as strong a direct Leadership → Results relationship as the researcher found through this project.

From a practical perspective, the strong Top Management Commitment → Quality Performance relationship that the researcher found ($\beta = 0.584$) may mean that top management have direct control over the outcomes (quality performance) as they may not want to rely on the system alone for product quality. The fieldwork on the SPC implementation case study failed to demonstrate that this is indeed the case convincingly, but this may be because the case study was something that which the top management had no ownership. The conclusion is that in a PCM context, Leadership has a direct effect on quality performance.

5.5.3 Test Results on H2

H2: Soft TQM factors contribute more to quality performance compared to hard TQM factors (RQ2)

The third Hypothesis was tested using SmartPLS 3 software, by treating hard TQM factors and soft TQM factors as second-order latent constructs, and taking the theoretical stance (inspired by the Toyota Way and similar theorisations) that soft factors are the factors that enable the application of hard factors to cause

results (Emiliani, 2006; Jayamaha et al., 2014; Rother, 2010; Wilson, Jayamaha, & Frater, 2018).

The path coefficients estimated by SmartPLS for the theoretical model that tests H2 are shown in Figure 5-10, while the t-statistics of these path coefficients and their significance are shown in Table 5-7. The results clearly indicate that all hypothesised paths are statistically significant at a 5% level (i.e. 95% CI).

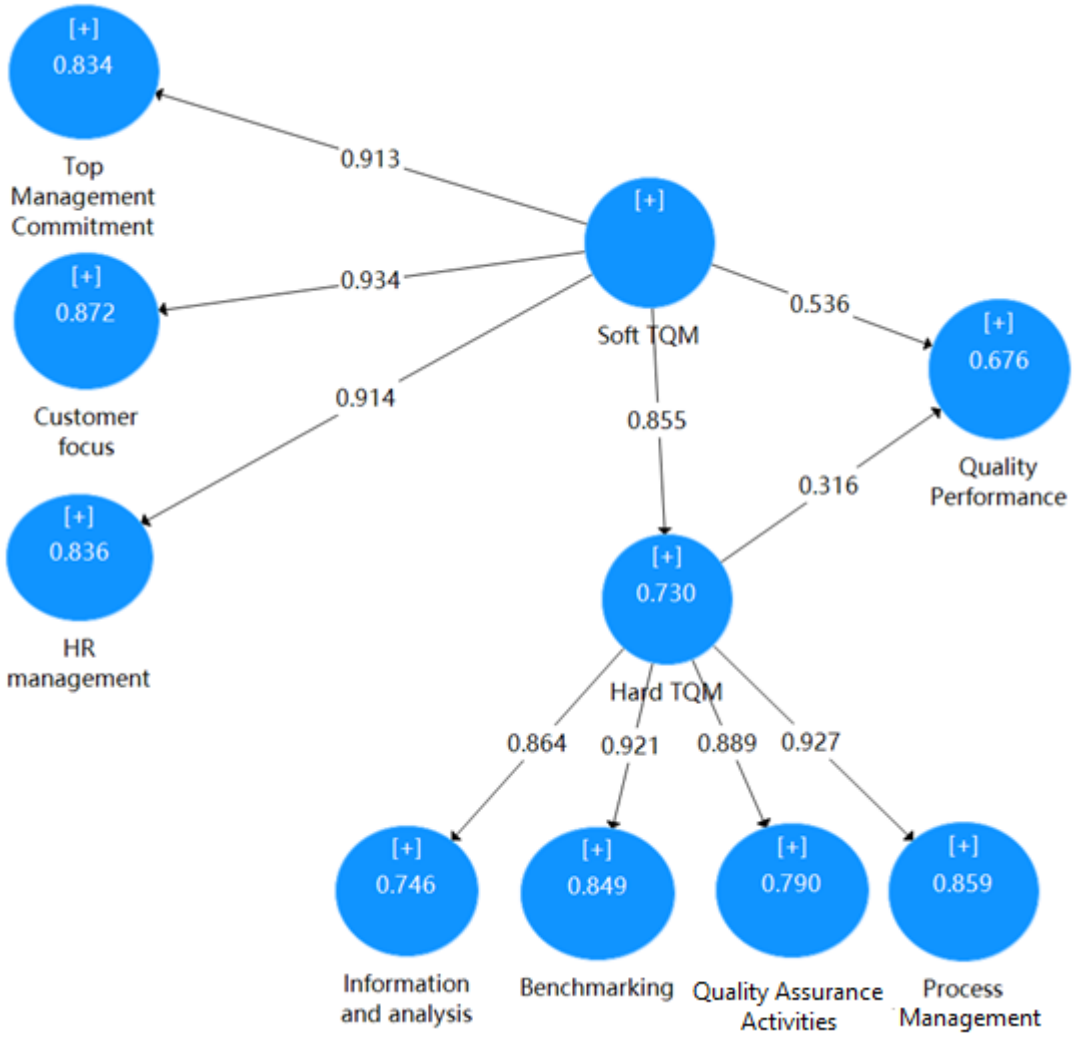


Figure 5-10 Estimated standardised path coefficients for the theoretical model on the relationship between hard factors and soft factors on quality performance

Given H2, the focus of the analysis should be on the inner relationships of the path model (i.e. the relationships between Soft TQM factors, Hard TQM factors and Quality Performance) and not on the outer relationships, which actually are

part of the operationalisation of Soft and Hard TQM factors (this is why the first three rows of Table 5-7 have been isolated from the rest). To be more specific Soft TQM Factors are taken as a whole and place these at a more abstract level (second-order level) than individual TQM factors (first-order level), which are in turn placed at a more abstract level than the individual survey items (not shown in Figure 5-10 to avoid complexity) that provide meaning to each TQM Factor. The same conceptualisation has been adopted to Hard TQM factors as well.

Table 5-7 Path Coefficients, 95% CI, t-values and P-values of the Effects of Soft and Hard Factors of TQM on Quality Performance

Hypothesised Structural paths	Estimated Path Coefficient	95% CI Lower Bound of the Path Coefficient	95% CI Upper Bound of the Path Coefficient	T Statistic	P Value
Soft TQM → Hard QTM	0.855	0.791	0.912	27.913	0.000
Hard TQM → Quality Performance	0.316	0.057	0.590	2.315	0.021
Soft TQM → Quality Performance	0.536	0.235	0.793	3.786	0.000
Hard TQM → Information and Analysis	0.864	0.817	0.916	33.809	0.000
Hard TQM → Process Management	0.927	0.893	0.954	61.228	0.000
Hard TQM → Quality Assurance Activities	0.889	0.841	0.923	39.991	0.000
Hard TQM → Benchmarking	0.921	0.881	0.955	58.383	0.000
Soft TQM → Customer Focus	0.934	0.902	0.691	62.407	0.000
Soft TQM→ Human Resource Management	0.914	0.881	0.946	55.964	0.000
Soft TQM→ Top Management Commitment	0.913	0.853	0.956	35.493	0.000

From the path coefficients reported in Figure 5-10 (or Table 5-7), the following effect sizes can be calculated:

Soft TQM → Quality Performance direct effect = 0.536
Soft TQM → Quality Performance indirect effect via Hard TQM = 0.855 x 0.316 = 0.270
Therefore, Soft TQM → Quality Performance total effect = 0.806

On the other hand, Hard TQM only has a direct relationship with Quality Performance, which is 0.316. Thus, it is argued that Soft TQM factors are more influential than Hard TQM factors in causing Quality Performance (a 0.806 effect versus a 0.316 effect). Thus, hypothesis H2 is accepted.

5.5.4. Test Results on H3

H3: Operators with working holiday visa participate less in quality-related decision making.

To test H3, one-way ANOVA was performed using Minitab. The level of participation in quality-related decision making was taken as the average score of Quality Assurance Activities (averaging the scores of QAA1 through to QAA5). The independent variable was taken as "Visa Type" — a factor that has 3 levels: NZ citizen/permanent resident, work visa holders, and working holiday visa holders (see Figure 5-5). The one-way ANOVA results are shown in Table 5-8. These results suggest that the visa type does not affect participation in quality assurance activities. The interval plot (Figure 5-11) shows more clearly why the test fails to reject the null hypothesis (overlapping 95% CI) that all factor levels have the same mean score. Thus, data failed to support H3, although it must be acknowledged that a small number of participants in the working holiday visa group (Figure 5-5) has led to H3 being unable to be supported by data.

Table 5-8 One-way ANOVA Results: Quality Assurance Activities Versus Visa Type

Null hypothesis	All means are equal
Alternative hypothesis	Not all means are equal
Significance level	$\alpha = 0.05$

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Visa type	3	1, 2, 3

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Visa type	2	1.715	0.8576	0.6	0.553

Error	73	104.792	1.4355
Total	75	106.507	

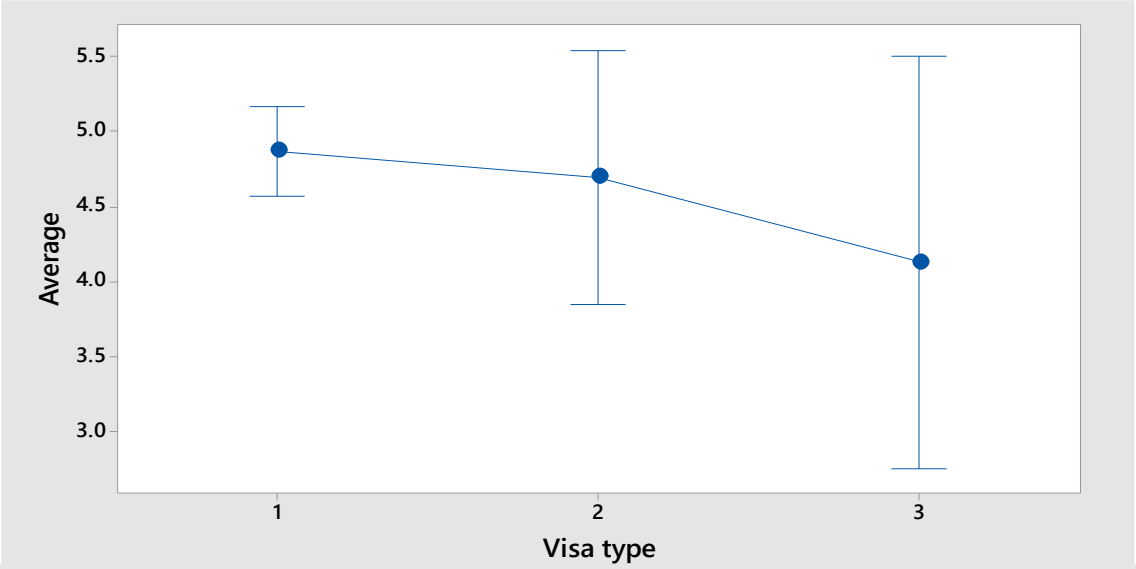
Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
1.19813	1.61%	0.00%	0.00%

Means

Visa type	N	Mean	StDev	95% CI
1	65	4.874	1.203	(4.578, 5.170)
2	8	4.7	1.047	(3.856, 5.544)
3	3	4.133	1.501	(2.755, 5.512)

Pooled StDev = 1.19813



1: NZ citizen/resident/permanent resident; 2: working visa holder; 3: working holiday visa holder

Figure 5-11 95% CI of means for three types of visas

5.6 SUMMARISING THE FINDINGS TO ANSWER RQ2 AND RQ4

The researcher hypothesised that access to information on the part of floor-level workers impeded SPC driven quality performance (H1). However, the researcher found that this was not to be. The researcher hypothesised that operators with working holiday visas participate less in quality-related decision making (H3) and this could impede SPC driven quality performance. As with H2, the researcher failed to support H3. However, people with working holiday visas can affect

quality performance unless the management is careful enough to ensure that these employees are not deployed in critical to quality activities. It is a pity that the researcher ran out of time to audit what types of work working holiday visa holders do!

Through structural equation modelling, the researcher demonstrated that the top management has both a direct and indirect impact on quality performance. All the critical success factors of TQM/SPC in the theoretical model (Figure 3-6) were found to have a positive impact on quality performance. These critical factors (enablers of TQM/SPC implementation success) are top management commitment, benchmarking, information and analysis, human resource management, quality assurance activities, customer focus, and process management.

RQ2 asks: “given the SPC programme, what are the critical enablers for implementing SPC in a PCM company”? In the previous chapter, through the SPC mini-journey that the researcher embarked with her team, she found that supportive management, correct SPC tools usage, operator and management training, process knowledge, technical support, awareness and above all willingness to change are potential enablers of SPC implementation. These enablers were put into context in this chapter by testing a theory that explains how the SPC/TQM enablers cause quality performance. More specifically, the researcher was able to validate the critical enablers of TQM/SPC (Table 5-6) in a PCM environment. In addition, the study showed that soft factors on TQM/SPC — top management commitment, customer focus, HR management — are more influential than hard factors of TQM/SPC (information and analysis, benchmarking, quality assurance activities, and process management). While this finding per se is nothing new, unlike prior studies, through this study, the researcher was able to quantify the relative effects to show by how much the former is more influential than the latter, which is something new to academia. For the above reasons, the researcher maintains that RQ2 has been answered reasonably well to achieve the second research objective.

RQ4 asks, “what are the enablers of quality performance and how do they cause quality performance”? This question has been answered comprehensively by testing the relevant underlying theory (see the theoretical model shown in Figure 5-8 as well as the path analysis results depicted in Table 5-6).

5.7 CHAPTER CONCLUSION

In this chapter, the researcher explained how RQ2 was answered more fully (RQ2 was partially answered in the previous chapter); the researcher also explained how RQ4 was answered comprehensively. By answering RQ2 and RQ4 adequately, the researcher was able to achieve the second and fourth research objectives of the study. The next chapter, sixth and final chapter of this thesis outlines the key outcomes of the study, its limitations, and the suggestions for further research.

Chapter 6 CONCLUSION

6.1 INTRODUCTION

This chapter outlines the key outcomes of the study, its limitations, and the suggestions for further research. The main goal of the research was to identify the critical success factors of SPC implementation success in a PCM company and explain how they affect quality performance. As a practitioner outcome, the research demonstrated a suitable framework to implement SPC in a PCM company.

6.2 KEY ACHIEVEMENTS

In this section, the researcher explains how the research objectives (repeated below for the convenience of the reader) were achieved through this research.

Research Objective 1: To identify a suitable SPC programme for a PCM company.

Research Objective 2: To identify enablers for implementing SPC in PCM.

Research Objective 3: To assess the suitability of SPC tools to handle a critical to quality variation problem in a PCM case study company.

Research Objective 4: To identify the enablers of quality performance in a PCM environment and explain how these enablers cause quality performance.

6.2.1 Achievements Against Objective 1

The researcher reviewed a vast number of papers related to SPC, in relation to total quality management and SPC programme and SPC implementation

frameworks. The six-step SPC implementation approach (Section 2.5.2, and Sections 4.2 through to 4.6) was chosen as a suitable SPC implementation framework in the PCM company. By trialing of six-step implementation approach in the company (results and discussion in Chapter 4) to solve a critical-to-quality problem (low process capability of maintaining the fill-weight of ingredients contained in a capsule, based on Cpk and Ppk ratios) the researcher was able to gain valuable insights on SPC implementation such as its applicability, user buy-in, and potential problem areas.

The wide tolerances used in the industry for characteristics such as fill-weight (particularly for dietary supplements) means that understanding and controlling variation is likely to be less of a challenging/demanding proposition than in precision engineering applications that work with tight tolerances. While user-buy in was good (there is a natural affinity between the industry and SPC and both rely on measurement and analysis, or in broader terms learning and action), one life-long lesson the researcher leaned is that quality improvement initiatives need to be justified both economically (e.g. a favorable benefit/cost ratio, a return on investment) and commercially (need to do what the customer wants and the specification is the best signal to know this).

Overall, the researcher feels that objective 1 has been successfully achieved.

6.2.2 Achievement Against Objective 2

Research objective 2 concerns identifying enablers for implementing SPC in PCM. This objective was achieved by marshalling evidence from the case study (SPC mini-journey covered in Chapter 4) and theoretical model building and empirical testing covered in Chapter 5. Using multiple streams of data is consistent with post-positivist paradigm used the researcher.

In Chapter 4, through the SPC mini-journey that the researcher embarked with her team, the researcher found that supportive management, correct SPC tools usage, operator and management training, process knowledge, technical

support, awareness and above all willingness to change are the enablers of SPC implementation. These enablers were put into context in Chapter 5 by positing a testable theory via extant literature to explain how SPC/TQM enablers cause quality performance (Figure 5.3 represents the theory as a latent variable path model). More specifically, the researcher was able to validate the critical enablers of TQM/SPC (Table 5-6) in a PCM environment, using the state-of-the art in latent variable path modelling (partial least squares-based path modelling was used). Moreover, the study showed that soft factors of TQM/SPC — top management commitment, customer focus, HR management — are more influential than hard factors of TQM/SPC (information and analysis, benchmarking, quality assurance activities, and process management). While this piece of information per se is nothing new, unlike prior studies, through this study, the researcher was able to quantify the relative effects to show by how much the former is more influential than the latter, which is something new to academia. To the researcher's surprise, the researcher found that on average, operatives have as much access to information as mangers have, to improve quality. In addition, the researcher found that on average, the participation level of working holiday visa holders (they work on three-month contracts) in quality improvement activities is the same as the participation of permanent and semi-permanent employees, on average. The reasons for these discrepancies were discussed in the previous chapter.

As a practical contribution, some suggestions were provided to quality practitioners on implementing SPC in a PCM environment; as mentioned earlier, the researcher found that the six-step SPC implementation approach works in a PCM context. The suggestions provided by the researcher may help PCM organisations contemplating on adopting SPC, on what areas their organisation need improvement. In the SPC-lead problem solving front (the problem was high variation in filling associated with capsules supplied as a dietary supplement), the researcher came across the following (more details in Chapter 4), in relation to high variation of fill-volume.

1) The powder should be well mixed, and the storage environment should conform to stipulated standards.

2) Parameters and conditions of the machine should be constantly checked during the manufacturing process.
3) Operators must perform in-process inspection and setting checks; all the findings should be reported to quality department.
4) The proper environmental conditions should be maintained; the operators should turn on dehumidifier if the room is humid.
5) Staff needs more training.
6) More staff is required.

The conclusion is that in achieving objective 2, the researcher has maintained a good balance between contribution to current body of knowledge on the fitness of SPC in a PCM context as well as contribution to practitioner community on how they might implement SPC, particularly in a PCM context. The generalisability of the findings has been re-visited at the end of this chapter (Section 6.4).

6.2.3 Achievement Against Objective 3

Research objective 3 concerns assessing the suitability of SPC tools in handling a critical to quality variation problem in a PCM context. This objective is closely related to objective 1. A single case study was conducted to achieve this objective, by way of embarking on a mini-journey of implementing SPC in the case study company. This SPC Mini journey began by introducing the six-step procedure described in Chapters 2 and 4 (see Section 2.5.2 and Sections 4.2 through to 4.6). A candidate process for statistical process control was identified via Pareto analysis. The flow chart was used to illustrate hard-shell capsule encapsulation process. Potential sources of variability sources were identified using a cause and effect diagram (Ishikawa diagram). After introducing the project plan to the operators including application of SPC tools that follow[8], 20

[8] Training of staff, initially the management and them the operators (Step 4 of 6) is very important for SPC and other continuous improvement methods to sustain (Summers, 2010). However, in this project, the training of the staff (more precisely, training of the staff involved in the quality improvement team) took place informally by dwelling in a real quality improvement problem. The reason for this is the tight time timeframes the research project must work with and want of a formal management decision to implement SPC.

capsules were collected from Batch 1 in an hourly interval; $\bar{X}$ - S control chart and process capability histogram were selected as key SPC tools to study process stability and capability respectively. After removing a special cause variation (sample 6), the correct value of process capability index Cpk was re-estimated via Minitab software. The capability slightly improved (Cpk = 0.74), but the result still indicated that the process capability was still below par.

The important outcome of the SPC mini-journey is not so much determining the current capability level of a process but the team (and to a certain extent top management) accepting SPC as a suitable technique for identifying and understanding variation in a process. The team learned that reducing the inherent variation in a process (common cause variation) to improve the capability of the process is a challenging proposition but methods as basic as the application of the PDSA cycle working towards continuous improvement or application of sophisticated statistically designed experiments such as Taguchi methods or capital intensive process redesigns remain as available options to reduce inherent process variation. As per the existing quality control system, that the fill weight for Batch 1 was deemed acceptable based on the guidelines used in the industry, despite experiencing a Cpk value less than 1.0 (a figure such as 1.33 would have been ideal if the consequences of breaching specification limits is severe).

Due to limited time frames SPC based on attributes counted via periodic sampling was not covered in this project but the work covered was sufficient (fit for purpose) to achieve the third research objective.

6.2.4 Achievements Against Objective 4

Objective 4 concerns identifying the enablers of quality performance in a PCM environment and explain how these enablers cause quality performance. This objective was purposely drafted in to formulate and test an underlying theory that accommodates SPC as a dominant quality management practice. The researcher found that early operationalisations of TQM are almost inseparable from SPC,

although TQM accommodates an umbrella of quality management practices and SPC is just one of them.

Two theoretical models were developed by the researcher for empirical testing based on the extant literature. The first theoretical model (see Figure 5-7 or 5-8) attempts to explain how TQM/SPC enablers cause quality-related outcomes, operationalised as quality performance. The second theoretical model (Figure 5-10) posits soft TQM/SPC factors and hard TQM/SPC factors as second order latent variables related to quality performance. The purpose of the second theoretical model is to estimate the relative contributions of soft factors and hard factors of TQM/SPC towards quality performance. The researcher made a conscious attempt to maintain connectivity between the SPC mini journey and theory formulation and testing to achieve objective 4.

Latent variable path modelling software SmartPLS was used to test the two theoretical models (latent variable path models) using data (76 responses) collected via a survey questionnaire. The cause and effect hypotheses involving the latent variables in both models were supported by data, which implies that the two hypothesised theoretical models are tenable. Regarding results on the first theoretical model, top management commitment was found to have both a direct effect and indirect effect on quality performance through the remaining enablers that act as mediators. Regarding results on the second theoretical model, soft factors of TQM/SPC were found to have a significantly greater effect on quality performance than the effect due to hard factors of TQM/SPC. While this finding per se is nothing new, unlike prior studies, through this study, the researcher was able to quantify the relative effects to show by how much soft factors are more influential than hard factors (a total effect of 0.836 versus 0.316), which is something new to academia.

6.3 CONTRIBUTION TO ACADEMIA AND QUALITY MANAGEMENT PRACTICE

The field work involving a trial SPC implementation, referred to as the SPC mini-journey (Chapter 4) was useful in testing the applicability of SPC in a PCM context. The importance of SPC enablers surfaced in the SPC mini journey. For PCM companies contemplating on SPC implementation can learn certain things from this study. One such learning is the six-step SPC implementation approach that was validated via the case study. Another learning is potential problem areas in SPC implementation such as economic and commercial justification for implementation. Therefore, the researcher argues that the case study part of the study has practitioner appeal.

The two theoretical models that the researcher developed and empirically tested via survey research puts TQM/SPC enablers in a perspective (Chapter 5). These models, particularly the second model brings new academic knowledge, as mentioned in the previous section. Theoretical models are useful to practitioners too, because these models can be used to understand successful TQM/SPC implementation as well as unsuccessful TQM/SPC implementation, reminding the quote of Kurt Lewin (1951): “there is nothing so practical than a good theory”.

6.4 LIMITATION AND FUTURE WORK

The study used non-probability sampling methods and self-selecting techniques involving data collected from one PCM company, albeit a large one. The study confronted the issue of representativeness. The findings of this study should not be projected to the wider manufacturing context. There is some homogeneity in PCM, but no two organisations have identical climates for quality improvement. If participants from other organisation, they may have different experiences.

Although it was hoped to receive a sizable number of questionnaire responses to constitute a large-enough subgroup of those holding working holiday visa (required for ANOVA), this did not come into fruition unfortunately. Since

employment of workers on a holiday visa is quite common in the industry and such workers do not represent the culture of the organisation (also they are less inclined to engage strongly in quality improvement activities), it is suggested that the authors study should be augmented to cover larger samples of working holiday visa holders (within or outside New Zealand). While the sample size of 76 responses for key analyses was adequate (> 67, the minimum sample required), a large sample data are highly valued in statistical modelling as large sample data generate more precise estimates (narrower confidence intervals), which is another reason to replicate this study.

Have said above, it is suggested that future studies may involve a random selection of several PCM companies, that include manufacturers of dietary supplements as well as manufacturers that produce more controlled medicines that are associated with tighter tolerances for quality characteristics (manufacturers of dietary supplements may be treated as a reference group). Another direction future research may head is towards conducting longitudinal studies to understand the sustainability of SPC in the long-run in the pharmaceutical manufacturing industry.

6.5 FINAL THOUGHTS

An important aspect in academic research is to contribute to the exiting body of knowledge as a new theory or a theory extension. The researcher's contribution belongs to the latter, where PCM was used as the delimiter (boundary) of the research. A practical contribution in academic research is bonus but the researcher made a conscious effort to deliver something useful to the practitioners.

This 90-credit masters research was constrained due to limited time and funding available to conduct the study. If the researcher were to conduct this research all over again, one thing she would have done differently was to do more preparation before presenting the results to senior managers. At high-level decision making, financial and commercial considerations of introducing something new, such as

SPC, becomes important. In retrospect, the researcher felt that more thought would have been given to this during project planning stage. Inclusion of an accountant in the quality improvement team would have done the trick and like all apprenticeships, this research taught some useful lessons to the researcher.

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APPENDIX

APPENDIX - A: LOW RISK NOTIFICATION

MASSEY UNIVERSITY
TE KUNENGA KI PŪREHUROA
UNIVERSITY OF NEW ZEALAND

Date: 09 October 2018

Dear Lu Cui

Re: Ethics Notification - **4000020219** - **Studying Statistical Process Control in a Pharmaceutical Contract Manufacturing Company**

Thank you for your notification which you have assessed as Low Risk.

Your project has been recorded in our system which is reported in the Annual Report of the Massey University Human Ethics Committee.

The low risk notification for this project is valid for a maximum of three years.

If situations subsequently occur which cause you to reconsider your ethical analysis, please contact a Research Ethics Administrator.

Please note that travel undertaken by students must be approved by the supervisor and the relevant Pro Vice-Chancellor and be in accordance with the Policy and Procedures for Course-Related Student Travel Overseas. In addition, the supervisor must advise the University's Insurance Officer.

A reminder to include the following statement on all public documents:
"This project has been evaluated by peer review and judged to be low risk. Consequently, it has not been reviewed by one of the University's Human Ethics Committees. The researcher(s) named in this document are responsible for the ethical conduct of this research.

If you have any concerns about the conduct of this research that you want to raise with someone other than the researcher(s), please contact Professor Craig Johnson, Director - Ethics, telephone 06 3569099 ext 85271, email humanethics@massey.ac.nz."

Please note, if a sponsoring organisation, funding authority or a journal in which you wish to publish requires evidence of committee approval (with an approval number), you will have to complete the application form again, answering "yes" to the publication question to provide more information for one of the University's Human Ethics Committees. You should also note that such an approval can only be provided prior to the commencement of the research.

Yours sincerely

Research Ethics Office, Research and Enterprise
Massey University, Private Bag 11 222, Palmerston North, 4442, New Zealand **T** 06 350 5573; 06 350 5575 **F** 06 355 7973
E humanethics@massey.ac.nz **W** http://humanethics.massey.ac.nz

APPENDIX - B THE SURVEY QUESTIONNAIRE

MASSEY UNIVERSITY
TE KUNENGA KI PŪREHUROA
UNIVERSITY OF NEW ZEALAND

A Questionnaire on the Quality Management System of a Pharmaceutical Contract Manufacturing Company

Dear Sir/Madam,

I am studying a Master's degree in Quality Systems at Massey University, New Zealand. As part of fulfilment of academic requirements, I am required to conduct a substantial research in my study area. The data required for my study will come from a questionnaire. The aim of my questionnaire is to study the operating climate of a pharmaceutical contract manufacturing company to understand which factors are more important than others in implementing objective quality control procedures such as Statistical Process Control. This study is confined to our company only due to resource limitations (especially time).

I seek your support in making my study a success by way of filling this questionnaire. It will take approximately 20 minutes of your valuable time to answer all the questions. The data you enter on this form will be processed confidentially. I would also like to mention that my study conforms to Massey University Ethics guidelines (the study was peer reviewed and deemed to low risk to people and my organisation). Please attempt to answer all the items. If you have questions, please don't hesitate to contact me. **If you are unsure about a particular item in the questionnaire, please leave it blank (too much guesswork affects the accuracy of my data).** Feel free to write down any comments at the end of the questionnaire. As you may want to may want to ensure that you are not personally identified, please drop off your duly completed questionnaire in the drop box placed near the clock in/out machine.

If you have any concerns about the conduct of this research that you wish to raise with someone other than me, you may contact my academic supervisor, Dr. Nihal Jayamaha, Senior Lecturer in the School of Engineering, Massey University (email N.P.Jayamaha@massey.ac.nz). The closing date of my questionnaire is 09 November 2018.

Thank you in advance for your support.

Best regards
Lu Cui (QA Officer)
School of Engineering and Advanced Technology
Massey University
Email: lucuiprc@gmail.com

Part A. General Information

Please tick the appropriate box for each question

1. You belong to the following age category:
   - ☐ 18-21 years
   - ☐ 22-25 years
   - ☐ 26-30 years
   - ☐ 31-40 years
   - ☐ 41-50 years
   - ☐ Over 51 years

2. You have worked in the pharmaceutical industry for:
   - ☐ Less than 6 months
   - ☐ 6 months to 1 year
   - ☐ 1-2 years
   - ☐ 2-5 years
   - ☐ 5-10 years
   - ☐ More than 10 years

3. Your highest educational qualification is:
   - ☐ High school certificate
   - ☐ Diploma degree
   - ☐ Bachelor's degree
   - ☐ Post-graduate Diploma and Honours degree
   - ☐ Master's degree and higher
   - ☐ None of above

4. You belong to the following employment category:
   - ☐ Higher than departmental manager
   - ☐ Departmental manager
   - ☐ Assistant manager
   - ☐ Supervisor
   - ☐ Coordinator
   - ☐ Team leader
   - ☐ QC
   - ☐ QA
   - ☐ Frontline worker (operator, sorting, packer, etc.)

5. Your Visa status is:
   - ☐ NZ citizen, resident, permanent resident
   - ☐ Working visa
   - ☐ Working holiday visa

Part B. For each of the questions below, circle the response that best characterises your level of agreement, where: 1 = Strongly Disagree, 2 = Disagree,..., 6 = Agree, and 7 = Strongly Agree

	Strongly Disagree	Disagree	Some-what Disagree	Neither Agree nor Disagree	Some-what Agree	Agree	Strongly Agree
Information and analysis							
1. Quality-related data (e.g. error rates, quality costs, defect rates, scrap, rework, returns, etc.) are available for quality improvement decision making in our company.	1	2	3	4	5	6	7
2. Quality-related data are available to frontline workers on time, in our company.	1	2	3	4	5	6	7
3. Quality-related data are available to supervisors and managers on time, in our company.	1	2	3	4	5	6	7
4. Our top management① use quality-related data in their decision-making.	1	2	3	4	5	6	7
5. Our middle management② use quality-related data in their decision-making.	1	2	3	4	5	6	7
6. Our frontline workers use quality-related data in their decision-making.	1	2	3	4	5	6	7
Top management							
7. Our top management executives assume responsibility for quality-related performance.	1	2	3	4	5	6	7
8. Our top management participate in the quality improvement process.	1	2	3	4	5	6	7
9. Our top management set objectives for quality-related performance.	1	2	3	4	5	6	7
10. Our top managers set quality goals that are specific to our company.	1	2	3	4	5	6	7
11. Quality issues related to our products and services attract the attention of our top managers.	1	2	3	4	5	6	7
Customer focus							
12. Our company is totally committed to creating satisfied customers.	1	2	3	4	5	6	7
13. Our company goals on product quality exceed customers' expectations.	1	2	3	4	5	6	7

① Top management: Managers above Departmental managers
② Middle management: Departmental managers, supervisors and team leaders, etc.

	Strongly Disagree	Disagree	Some-what Disagree	Neither Agree nor Disagree	Some-what Agree	Agree	Strongly Agree
14. Executives in our company demonstrate the importance of customer satisfaction through their action.	1	2	3	4	5	6	7
15. Employees in our company know which attributes of the products or services are valued by the customers.	1	2	3	4	5	6	7
16. We use information collected from our customers (e.g. customer needs, feedback on current products) in designing new products and services.	1	2	3	4	5	6	7
17. Our top management frequently contact the customers.	1	2	3	4	5	6	7
18. We give priority to resolving customer complaints.	1	2	3	4	5	6	7
19. Our employees are being encouraged to satisfy the customers.	1	2	3	4	5	6	7
Human resource management							
20. Employee involvement program③ are implemented in our company.	1	2	3	4	5	6	7
21. Operators in our company participate in product quality decisions.	1	2	3	4	5	6	7
22. Employees in our company hold responsibility for the output they provide towards the processes.	1	2	3	4	5	6	7
23. Quality awareness building among employees is an ongoing activity in our company.	1	2	3	4	5	6	7
24. Our company uses objective measures to measure employee morale and/or satisfaction.	1	2	3	4	5	6	7
25. Quality-related training is given to operators throughout our company.	1	2	3	4	5	6	7
26. Our company provides training on the use of basic statistical techniques/quality tools (e.g. histograms, line graphs, scatter plots, cause and effect diagrams, control charts) to relevant employees.	1	2	3	4	5	6	7

③ Employee involvement program: Empower employees, provide information and training to enable employees to be in control of their work and to be able to participate in problem solving and decision making of certain processes.

	Strongly Disagree	Disagree	Some-what Disagree	Neither Agree nor Disagree	Some-what Agree	Agree	Strongly Agree
Benchmarking④							
27. Our company studies the best practices of other companies to get ideas about how to do things better.	1	2	3	4	5	6	7
28. Our company compares the current quality levels for products and services features with those of competitors.	1	2	3	4	5	6	7
29. Our company compares the current quality levels for products and services features with those of world leaders.	1	2	3	4	5	6	7
30. Our company compares the current process quality levels with those of competitors.	1	2	3	4	5	6	7
Quality assurance activities							
31. Our company endeavours to (tries to) reduce scrap levels⑤ by applying scientific methods (e.g. inspection, brainstorming, Kaizen walk etc.).	1	2	3	4	5	6	7
32. Our company endeavours to reduce rework levels⑥ by applying scientific methods.	1	2	3	4	5	6	7
33. Our company endeavours to increase productivity by applying scientific methods.	1	2	3	4	5	6	7
34. Our company's endeavours to reduce manufacturing throughput time⑦ by applying scientific principles.	1	2	3	4	5	6	7
35. Our company endeavours to reduce cost (e.g. cost of poor quality) by applying scientific principles.	1	2	3	4	5	6	7
Process management							
36. Our company reviews a new product design before the product is produced.	1	2	3	4	5	6	7
37. Our company provides product specifications to employees engaged in quality control activities.	1	2	3	4	5	6	7

④ Benchmarking is a quality management tool/approach that can be used to study industry best practices on processes. Benchmarking helps the company to find better ways of doing things very efficiently/effectively, rather than re-inventing the wheel!

⑤⑥Compared to rework level, scrap level means the condition of the defect is so poor that is unable to be fixed through rework.

⑦Manufacturing throughput time: Time required for raw material to be converted into finished goods.

	Strongly Disagree	Disagree	Some-what Disagree	Neither Agree nor Disagree	Some-what Agree	Agree	Strongly Agree
38. Our company possesses clearly documented product procedures and work instructions for the employees.	1	2	3	4	5	6	7
39. Our company conducts a proof of concept (i.e. prove the feasibility) for all new product design process.	1	2	3	4	5	6	7
40. Our company designs process that minimize the chances of employee errors.	1	2	3	4	5	6	7
41. Our company provides clear work instructions to the employees.	1	2	3	4	5	6	7
Quality Performance							
42. We have been able to increase customer satisfaction over the past 2 years.	1	2	3	4	5	6	7
43. We have been able to maintain market share over the past 2 years.	1	2	3	4	5	6	7
44. We have been able to reduce product defect rates over the past 2 years.	1	2	3	4	5	6	7
45. We have been able to improve productivity over the past 2 years.	1	2	3	4	5	6	7
46. We have been able to reduce waste (overproduction, unnecessary motion and transportation, waiting times, over-processing and unused time and creativity of employees) over the past 2 years.	1	2	3	4	5	6	7

Comments (if any)

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