Investigation of the application of Statistical Process Control into Low Volume Manufacturing

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A Thesis presented for the degree of
Master of Science

Department of Engineering
University of Durham
United Kingdom
April 2022

Dedication

To my parents, for always loving and supporting their daughters. For taught us to pursue our dreams and do what makes us happy. For inspiring us to work hard for the things that we aspire to achieve. Also, to my little sister, I am grateful for having you in my life. Mom and dad, for all your love, thank you.

Abstract

Statistical process control (SPC) into Low Volume Manufacturing environment face a challenge applying SPC techniques. SPC is commonly used for quality control and improvement in the manufacturing sector. In the early 1920s, Dr Walter Shewhart developed the control chart employed to monitor a process over time, where the first data is collected and then plotted on a graph. Moreover, a control chart is composed of a Central Line (CL), the Upper Control Limit (UCL) and the Lower Control Limit (LCL). Parameters and control limits are calculated to analyze the control chart, requiring twenty to twenty-five subgroups of data, with three to five values per subgroup, or at least sixty measurements. However, collect this amount of data is difficult in certain production processes, where the lot size could even be one and it could take weeks or months to accumulate enough data to estimate the process parameters.

Statistical process control is a challenge in some scenarios such as startup production, different or individual parts in the same production line, or production of customized products. In these cases, there is not enough amount of data to compute the parameters to monitor the process. Therefore, special techniques and statistical methods are required. Some authors developed self-starting control charts and alternative methods for short-run production, e.g. Q charts, Exponentially Weighted Moving Average (EWMA) and Cumulative sum (CUSUM). This thesis studies the performance of these SPC tools, implementing a Low Volume Statistical Process Control (LV-SPC) model through an Excel spreadsheet, analyzing the production process data from companies that are performing low volume manufacturing.

This work provides an interpretation and explanation about statistical process control into low volume manufacturing, analyzing the application of different SPC methods developed for short production runs based on data collected from different companies. Data collected was processed to individual measurements from the process deviation rather than the mean values. Converting the data to individual values the SPC methods for low volume manufacturing are viable to use. Also, performance, effectiveness, and how it can be further implemented were discussed.

Declaration

The work in this thesis is based on researching Statistical Process Control into Low Volume Manufacturing, carried out at the Department of Engineering, Durham University, United Kingdom. No part of this thesis has been submitted elsewhere for any other degree or qualification and it is all my own work unless referenced to the contrary in the text.

Acknowledgements

First, I would like to express my sincere gratitude to my supervisor Dr Oliver Vogt for his guidance throughout this research project. I am extremely grateful for his unconditional support and always encourage me to finish my thesis. For your time and patience, Thank you. You are an excellent supervisor. I also would like to say special thanks to my husband Ivan who has been a great source of support during this time. Finally, to Steven Cox, and all the people who participated in the data collection stage, without their help this project would have not been the same.

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List of Acronyms

CL Central Line.

CNC Computer Numerical Control.

CUSUM Cumulative sum.

EWMA Exponentially Weighted Moving Average.

LCL Lower Control Limit.

LV-SPC Low Volume Statistical Process Control.

MA Moving Average.

MR Moving Range.

SPC Statistical Process Control.

UCL Upper Control Limit.

Nomenclature

λ	Constant which determines how old or recent is the data
μ	Mean value
$\overline{\overline{x}}$	Grand average of each average subgroup
$\overline{x}$	Average of a subgroup of samples
σ	Standard deviation
σ^2	Variance
K	Multiple value of sigma
k	Number of samples
L	Takes the value of the standard deviation
p	Denotes the number of variables
X	Individual observation
x_{max}	Largest value of a group of samples
x_{min}	Smallest value of a group of samples

Chapter 1

Introduction

1.1 Introduction

Statistical Process Control (SPC) was introduced by W. Shewhart, creating important statistical tools for analyzing and monitoring the variability of manufacturing processes. Since variability can only be described in statistical terms, SPC methods play a predominant role in quality improvement, in particular Control Charts [1]. The primary objective of SPC is to detect the presence of variability and provides graphical evidence when a process is in control or not, with the purpose to perform corrective actions [1].

Shewhart control charts or traditional statistical process control tools have been widely adopted and successfully applied in mass production industries. Traditional SPC methods have contributed improving process performance over time, monitoring the stability of the processes [2]. Hence, SPC became a vital statistical tool for continuous quality improvement and an 'strategy for reducing variability' [3].

However, the application of traditional SPC methods in low volume manufacturing environments have had many difficulties [4]. Production lines of many companies have been changed drastically in the last few decades, these are getting shorter and more complex. In addition, industries are producing a large number of different products in small quantities on the same production line [5]. Therefore, many authors have simulated data with these characteristics to study the effectiveness of alternative SPC methods in order to comprehend short and mixed production runs scenarios [6].

A realistic example of short production run is the multifunction Computer Numerical Control (CNC) machining centre in a workshop, with a production of small batches and complex parts. Consequently, this process involves that the number of variables is not the same from one batch to another, measurements of several related variables, and different target values [4, 6]. Therefore, traditional SPC methods are less effective.

Companies executing these conditions of production runs have not been able to apply SPC and cannot realize the associated effective process monitoring. They are facing some problems due to the limited amount of available data in such situations. Under these circumstances, some authors have been developed alternative methods for short run production processes [4, 7].

This thesis is at the current limits of understanding of the application of SPC into low volume manufacturing. The reason is that most of the available research and application of SPC consulted during this study has been developed for specific process characteristics. This means that the implementation of SPC into low volume manufacturing is developed to each individual case. Therefore, this work limits its understanding of the application of SPC into low volume for the cases studied in the following chapters.

1.1.1 Introduction to Statistical Process Control (SPC)

Statistical Process Control (SPC) techniques have been proven useful for control procedures. These methods are used to monitor and detect variation sources in a process, in order to implement statistical analysis and improve manufacturing processes [8]. Therefore, SPC has a significant impact measuring the process variability, and in consequence allowing to find the variation causes [9].

In SPC, the process has two different states, in control or out of control. The process is In Control if special causes are not affecting it. Otherwise, the process is classified as Out of Control [1]. Also, In Control and Out of Control state depends on the control limits, when data points are between them, the process is considered in control. On the other hand, in case the data is located outside the control limits, the process will be out of control, as it is shown in the figure 1.1. Moreover, it can be appreciate that the control chart is constituted by the Central Line (CL), Upper Control Limit (UCL), Lower Control Limit (LCL) and the plotted data points [10].

CL, UCL and LCL are calculated by

$$UCL = \mu + z\sigma \tag{2}$$

$$CL = \mu \tag{3}$$

$$LCL = \mu - z\sigma \tag{4}$$

Where μ is the mean of the measured parameter, z is the distance from the control limit to the center line, expressed in units of standard deviation. It is generally calculated from the normal probability distribution, and σ is the standard deviation of the measured parameter. Commonly, μ and σ are unknown, they need to be estimated from historical data.

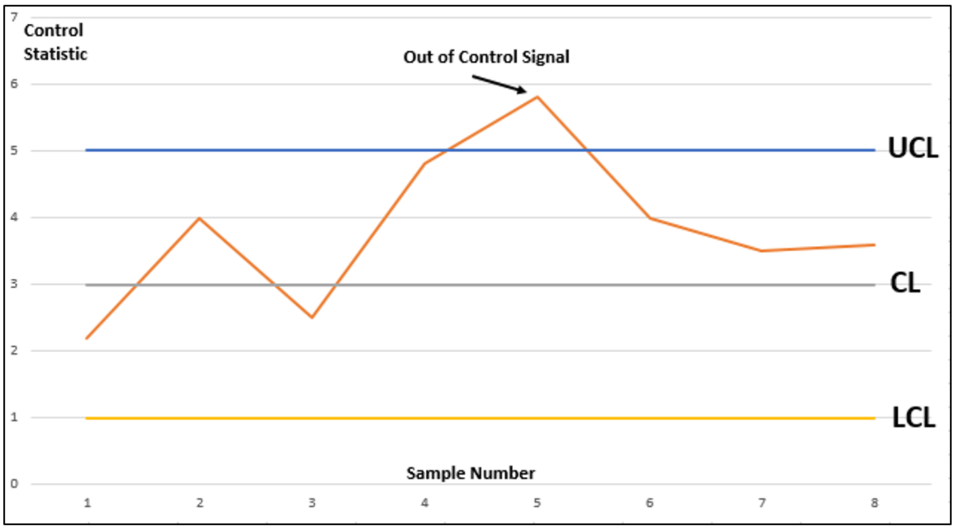


Figure 1.1: Control Chart

Most of the SPC tools are used during on-line process monitoring and are usually implemented in two phases. In phase I, it is required to collect adequate amount of data to build the control chart [10]. Thus, the control chart from Phase I is used to monitor the process and detect shifts, and this is considering Phase II [11]. Hence, some authors provided a hard stance arguing that '20 to 25 subgroups of data, quite often 3 to 5 samples per subgroup' is a requirement to calculate trial control limits [12]. This is an important condition to determinate the effectiveness of statistical process control charts.

On the contrary to mass production, in low volume manufacturing the data is not enough to compute the process parameters or control limits to construct the graph in Phase I. In such situation, traditional control charts such as Xbar, R, and S chart are less effective. Therefore, the control limits are not reliable to monitor the production process. Also, the probabilities of false alarms significantly increase, this occurs when a point plotted out the control chart limits, indicates an out of control signal, although the process is in control. Hence, some authors developed alternative methods for low volume manufacturing such as Q statistics, EWMA and CUSUM charts [11, 13].

1.1.2 Overall aim

The main scope of this thesis is to implement SPC methods for short production runs for the industry of Low Volume Manufacturing. In order to achieve the aim of this work, this research has been divided into three main objectives, Literature Review, Monitoring Control Charts for Short Production Processes and, Results and Discussion.

1.1.3 Thesis Objectives

The thesis objectives are explained in the following points:

Literature Review: review the papers related to statistical process control into low volume manufacturing.

Monitoring Control Charts for Short Production Processes: analyze the application of different SPC methods developed for short production runs based on data collected from different companies.

Results and Discussion: compare their performance, effectiveness, and how it can be further implemented, allowing workers in the floor shop to take advantage of the benefits to apply SPC methods.

1.1.4 Methodology and Organization

The primary method used in this thesis is the statistical analysis generated on a simple Microsoft Excel software. In the first section, this document provides an overview of the existing research on short-run statistical process control. Secondly, alternative methods to apply SPC are introduced and discussed. In the next section, it can be found the data collected from Merck and Durham University Engineering Workshop; Also, the Low Volume Statistical Process Control model for different short-run control charts is presented. In the final part, the results and discussion of the statistical analysis is provided. And finally, conclusions and possible further work in the area are given.

Chapter 2

Literature Review

2.1 Introduction

In this chapter, the selection of the methods needed to implement statistical process control in low volume manufacturing is presented. In the first part of the literature review, explanations of the traditional SPC methods are introduced. Secondly, alternative methods for statistical process control in low volume manufacturing are given, followed by previous work where the low volume SPC is used for process monitoring.

2.2 Traditional Statistical Process Control

The traditional Shewhart control charts are useful for the process monitoring of both the mean value and the variability of the quality characteristic or critical variable. The most common methods applied are the Xbar chart which plots the mean or the average of all subgroups sample, R chart plotting the range, and S charts which plots the variance or standard deviations, all of them estimate the dispersion of the data [7]. To construct traditional control charts is necessary to compute the sample averages of the data, the difference between largest and smallest values in a data set, and standard deviation respectively for each traditional SPC method. Moreover, Montgomery and Quesenberry have recommended 20 to 25 samples of subgroups of size between three or five [7, 10]. In order to understand the traditional methods of statistical process, they are discussed as follows.

2.2.1 Xbar, R and S Chart

The Xbar chart is a method used to detect changes of the process mean. It analyses the behaviour of the sample averages. The Xbar values are computed as equation 1, where Xbar ($\overline{X}$) is the average of the sample and n is the size number [7].

$$\overline{X} = \frac{x_1 + x_2 + \cdots + x_n}{n} \quad (1)$$

Once Xbar is calculated, the Xbar values are plotted on the control chart, and the parameters such as the central line and the control limits are computed to construct the control chart [14]. The central line is the mean μ of the process as indicate in equation 1,2 and 3. The UCL and LCL are obtained from the 3-sigma control limits, 3σ is the range that Shewhart discovered, where his process engineers could intuitively identified two categories of variation between common cause and special cause, and it is based from his personal experience. The control limits are given by equations 2 and 4 [7].

To measure variations, statisticians and analysts use a metric known as the standard deviation, also called sigma. Sigma is a statistical measurement of variability, showing how much variation exists from a statistical average.

$$UCL = \mu + 3\sigma \quad (2)$$

$$CL = \mu \quad (3)$$

$$LCL = \mu - 3\sigma \quad (4)$$

Standard deviation or sigma is used as a metric to calculate the variability of the process. To understand this indicator, consider the normal distribution or probability distribution. Normal distribution requires the mean and standard deviation to describe it; It is illustrated in figure 2.1, which looks like a bell curve. When looking at this figure, it can be noticed that there are three sections under the curve that are marked off with percentages. Each of these sections are an equal distance on either side of the average value. The distance represents multiples of the one standard deviation of the population and are labeled as σ, 2σ, etc.

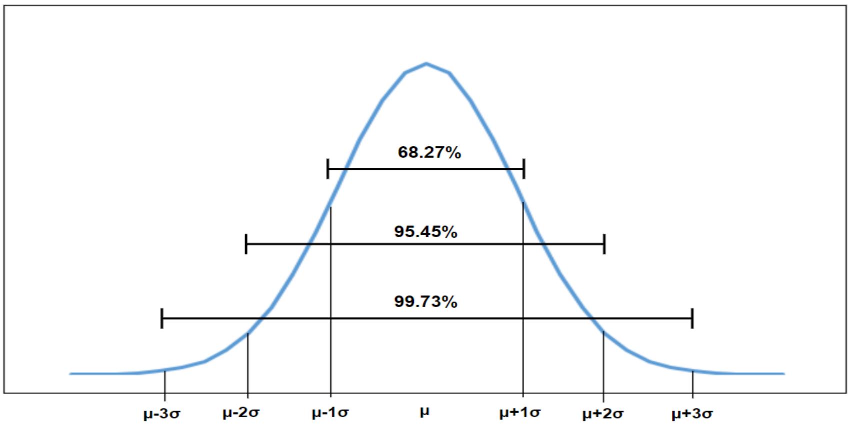


Figure 2.1: Normal distribution

The total area bounded by the normal distribution curve is 100% or 1. However, note that the 68.27% of the data is within the $\mu \pm 1\sigma$ interval, 95.45% is between $\mu \pm 2\sigma$, and about 99.73% will be contained in the $\mu \pm 3\sigma$ interval. Consequently, the upper and lower control limits obtained by equations 2 and 4 are divided into three standards deviation away from the mean [15,16]. For this reason, the resulting interval of upper and lower limits includes 99.73% of the observations as long as the process is in control.

Moreover, to estimate the process parameters in the previous formulas is assuming that the mean μ and the standard deviation σ are known values [7]. However, sometimes the mean μ and the standard deviation σ are not known. Therefore, they must be estimated. Equation 5 is used to calculate μ, where $\overline{\overline{x}}$ is the grand average of each average subgroup $\overline{x}_n$. There are m samples per subgroup to calculate $\overline{x}_n$, and n subgroups are used to calculate $\overline{\overline{x}}$. Also, the standard deviation is estimated with equation 6, where x is the sample value [7].

$$\overline{\overline{x}} = \frac{\overline{x}_1 + \overline{x}_2 + \cdots + \overline{x}_n}{n} \tag{5}$$

$$\sigma = \sqrt{\frac{\sum(x - \overline{x})}{n - 1}} \tag{6}$$

The R chart is another method to monitor changes in the process, as well as to determine the dispersion amount in a data set. The R value is calculated with equation 7, which is the difference between the largest and smallest values in a sample [10].

$$R = x_{max} - x_{min} \tag{7}$$

Where R is the range value, x_{max} is the largest value of the sample, and x_{min} is the smallest value of the sample. Moreover, the average of the $R_1 + R_2 + \ldots + R_m$ values is computed by using equation 8, to be plotted as the central line of the control chart.

$$\overline{R} = \frac{R_1 + R_2 + \cdots + R_m}{m} \tag{8}$$

Where $\overline{R}$ is the average of the range of the m samples, m is the number of samples, and the formula of $R_1 + R_2 + \ldots + R_m$ is the summation f the range value of each sample. Once the central line is obtained, the control limits are computed to monitor the process. The upper and lower bounds are calculated as equations 9 and 10 [7, 10].

$$UCL = D_4\overline{R} \tag{9}$$

$$UCL = D_3\overline{R} \tag{10}$$

Where the constants D_3 and D_4 are tabulated according to the n value in the following table [7]:

Moreover, the S chart uses the standard deviation to construct the control chart. Equation 11 is used to estimate the standard deviation for each sample, and equation 12 is used to compute Sbar ($\overline{S}$), which is the central line on the S char [7].

Chart for Ranges					
Factors for Control Limits					
n	d_3	D_1	D_2	D_3	D_4
2	0.853	0	3.686	0	3.267
3	0.888	0	4.358	0	2.574
4	0.88	0	4.698	0	2.282
5	0.864	0	4.918	0	2.114
6	0.848	0	5.078	0	2.004
7	0.833	0.204	5.204	0.076	1.924
8	0.82	0.388	5.306	0.136	1.864
9	0.808	0.547	5.393	0.184	1.816
10	0.797	0.687	5.469	0.223	1.777
11	0.787	0.811	5.535	0.256	1.744
12	0.778	0.922	5.594	0.283	1.717
13	0.77	1.025	5.647	0.307	1.693
14	0.763	1.118	5.696	0.328	1.672
15	0.756	1.203	5.741	0.347	1.653
16	0.75	1.282	5.782	0.363	1.637
17	0.744	1.356	5.82	0.378	1.622
18	0.739	1.424	5.856	0.391	1.608
19	0.734	1.487	5.891	0.403	1.597
20	0.729	1.549	5.921	0.415	1.585
21	0.724	1.605	5.951	0.425	1.575
22	0.72	1.659	5.979	0.434	1.566
23	0.716	1.71	6.006	0.443	1.557
24	0.712	1.759	6.031	0.451	1.548
25	0.708	1.806	6.056	0.459	1.541

Table 2.1: Factors for R control limits

$$S_i = \sqrt{\sum_{i=1}^{n} \frac{(x-\overline{x})^2}{n-1}} \tag{11}$$

$$\overline{S} = \sum_{i=1}^{k} \frac{S_i}{k} \tag{12}$$

Where S_i is the standard deviation of each sample, X_i is the average of each sample, $\overline{X}$ is the average of the average samples, and n is the number of samples. Moreover, equation 12 is used to calculate the central line of the chart or the $\overline{S}$ value. Where $\overline{S}$ is the average of the samples standard deviation, S_i the estimated standard deviation of each sample, and k is the number of samples [7].

2.2.2 Summary of Traditional SPC Methods

The control charts described above have been successfully applied in mass production industries, where the number of samples required to build the control charts is available, and collect the required amount of data is not an issue. On the other hand, these traditional methods are not useful in low volume manufacturing due to insufficient data to estimate the control limits and monitor the production process. To solve this situation, alternative methods considered for short-run production are explained in the next section.

2.3 Low Volume SPC Methods

Considering the limitations of traditional SPC techniques, many alternatives and adaptations of these methods have been developed to allow every company to take advantage of the power of SPC methods, even if lot sizes are limited. This chapter, gives more comprehensive review of techniques proposed for short runs along with possible methods. Also, provides its own contribution collecting real data from different companies in order to apply statistical analysis.

Low Volume manufacturing refers to processes in which production runs are in small lot size. Thus, implement traditional SPC methods such as Xbar, R or S Charts has become a problem, due to the limited amount of data. Therefore, in this literature review a few important methods for low volume have been introduced. In this research the methods taking into account are, Moving Average (MA) and Moving Range (MR) for individual measurement, Exponentially Weighted Moving Average (EWMA), Cumulative sum (CUSUM) and Q Chart. The Q Chart method was proposed by Quesenberry to detect changes in the process parameters during the initial state. This method does not require a large amount of historical data or a start-up stage [17].

The EWMA chart plots the exponentially-weighted moving average of all prior sample means, combining that new subgroup average with the running average of all preceding observations. Therefore, EWMA weights samples in geometrically decreasing order so that the most recent samples are weighted most highly while the most distant samples contribute very little [18]. The EWMA chart is useful to detect small shifts in the process, particularly in the early or start-up phases. The CUSUM chart represents the cumulative sum of all deviation from the mean data up to the current time point. The CUSUM method is focused on detecting small shifts in the process mean parameter. EWMA and CUSUM methods use historical data as well as the current data point to construct the control charts and determinate when a shift occurs [18, 19]. Therefore, a few useful methods will be studied and analyzed in order to implement Statistical Process Control into short production runs.

2.3.1 Moving Range (MR)

Control charts for individual measurements are used to monitor individual values and the variation of a process based on samples taken from a process over time, use the moving range of two successive observations to measure the process variability. Moreover, this charts attempt to maximize the information obtained from the limited amount of available data [20]. The Moving Range control chart is used when the parameter is measured once, and is efficient to detect a sudden shift in a process.

For a sequence of individual observation X_1, X_2,...,X_N, the moving range MR_i is given by the following equation 13

$$MR_i = |X_i - X_{i-1}| \quad for \quad i = 2, ..., N \tag{13}$$

which is the absolute value of the first difference (e.g., the difference between two consecutive data points) of the data.

The moving range control limits are given below

$$UCL = \overline{X} + 3\frac{\overline{MR}}{1.128} \tag{14}$$

$$CL = \overline{X} \tag{15}$$

$$UCL = \overline{X} - 3\frac{\overline{MR}}{1.128} \tag{16}$$

where $\overline{x}$ is the average of all the individuals and $\overline{MR}$ is the average of all the moving ranges of two observations, and d2 is an expected value of the sample range of n independent, normally distributed random variables with the same mean and a standard deviation of 1. As n increase, the constant value is also changing. For n=2, d2 is equal to 1.128, that corresponds to a moving range of length 2 [21].

2.3.2 Exponentially Weighted Moving Average (EWMA)

The Exponentially Weighted Moving Average (EWMA) method was introduced by Roberts between 1959 and 1966 as an alternative control chart to detect small shifts in the process [19]. EWMA is also a good alternative for detecting small shifts, and they can be used to detect increases or decreases in the process mean, and to initiate corrective actions when a shift is detected. Also, they can be applied to a wide range of characteristics and design, EWMA chart detects the shift whereas the Shewhart does not [22].

The EWMA or Z value is the geometrical moving average considering the current data point and is defines as equation 17.

$$Z_i = \lambda X_i + (1 - \lambda) Z_{i-1} \tag{17}$$

Where $0 < \lambda \leq 1$ and λ is a constant and starting values for $i = 1$ is the process target as $Z_0 = \mu_0$ also, in some cases the mean value is used as the staring value as $Z_0 = \overline{S}_0$.

To obtain the EWMA Z_i for $j = 2, 3, 4, ...$ previous Z values are considered to obtain the following values as equation 18.

$$Z_i = \lambda \sum_{j=0}^{i-1} (1 - \lambda)^j x_{i-j} + (1 - \lambda)^i Z_0 \tag{18}$$

Where $x_i - j$ is the observation at the time i. Moreover, the central line and the control limits are calculated in order to construct the EWMA control chart, using the following equations.

$$UCL = \mu_0 + L_\sigma \sqrt{\frac{\lambda}{(2-\lambda)}[1-(1-\lambda)^2 i]} \tag{19}$$

Central line $= \mu_0$

$$LCL = \mu_0 - L_\sigma \sqrt{\frac{\lambda}{(2-\lambda)}[1-(1-\lambda)^2 i]} \tag{20}$$

The process parameters for the EWMA chart are the L and λ values where L takes the value of the standard deviation or sigma and is recommended to give a value of three, as the 3σ limits. The λ value is the parameter which determines how old or recent is the data considered to calculated the Z value. Usually, λ takes values of 0.05, 0.10 and 0.20, if this value is one, it considers the most recent data. On the contrary, small values of λ close to 0 give more weight to past data because $\lambda = 1$ implies that only the most recent measurement influences the EWMA statistic. Thus, a large value of λ closer to 1 gives more weight to recent data and less weight to older data and a small value of λ closer to 0 gives more weight to older data. To detect smaller shifts, it is necessary to use smaller values of λ. The EWMA chart is suitable for detecting small shifts in the early phases of the process.

For detecting step shifts and linear trends based on individual observations, EWMA charts are found to be much more effective than other procedures, MacGregor and Harris (1993) [23] stated that this method provides a good effectiveness in the absence of historical data, this monitoring procedures initiate at the 3rd observation where the first two are used to provide some initial estimates of the mean and the standard deviation, resulting in some essentially self starting procedures.

2.3.3 Cumulative Sum (CUSUM)

C statistic for CUSUM method is the cumulative sum of the deviations of the sample values from a target value. This method was introduced by Page (1954, 1961). Rather than examining the mean of each subgroup independently, the CUSUM chart shows the accumulation of information about current and previous samples [24]. For this reason, the CUSUM chart is generally better than the $\overline{x}$ chart for detecting small shifts in the mean of a process. Moreover, in order to effectively apply CUSUM procedure, it is well understood that successive values for which the sum is accumulated should be independent and identically distributed [25].

To estimate the CUSUM values, the equations (17) and (18) have been used.

For C_0 use the equation below:

$$C_i = \sum_{j=1}^{i} (\overline{x}_i - \mu_0) \tag{21}$$

where $\overline{x}_i$ is the average of the sample value and μ_0 is the mean value. Moreover, to compute C_1, C_2, ... use equation 22.

$$C_i = \sum_{j=1}^{i} (\overline{x}_i - \mu_0) C_{i-1} \tag{22}$$

Once the CUSUM values are calculated, the next step is estimated the control limits to build the control chart, based on the tabular CUSUM method. The tabular CUSUM method for monitoring the process requires two process parameters, a reference value k, which tunes the CUSUM to be particularly sensitive to a specific anticipated shift. Also, the H value or decision interval, which is made up of horizontal lines as a lower and upper control limits, it is calculates as 5σ . This method calculates the statistics C^+ and C^- because it accumulates derivations from μ_0 that are above and below the target. Thus, if C^+ and C^- are outside the decision interval H, the process is considered to be out of control [26]. To estimate the C statistics for the tabular CUSUM, use the equations 23 and 24 where the starting values are $C_0^+ = C_0^- = 0$.

$$C_i^+ = max[0, x_i - (\mu_0 + K) + C_{i-1}^+] \tag{23}$$

$$C_i^- = max[0, (\mu_0 + K) - x_i + C_{i-1}^-] \tag{24}$$

Where K is a multiple value of sigma, commonly of 0.5

CUSUM charts are useful for a self-starting procedure as well as $Q - charts$ and one of the best options when detecting small shifts in the process mean is important; this method can detect changes in both the location and dispersion parameters [27]. CUSUM uses the current data point as well as all historical data to determine whether an assignable cause has occurred.

2.3.4 Q Statistics

Q charts have been introduced by Quesenberry in 1991, these methods are an innovative approach to process control, particularly pertinent to short run processes and processes during the start up phase [28]. Moreover, these Q charting procedures enable to begin monitoring the process with the first units or samples of production whether or not prior knowledge of the process parameters is available, Furthermore, for the case where no relevant data is available in advance of a production run the control parameters are estimated and updated sequentially from the current data [29].

Quesenberry [28] developed Q chart based on Q statistics for the mean and variance parameters. Q charts are given for different situations; For example, in which both, either or neither of those values are known, according to the parameters that are known about the process. Moreover, Quesenberry proposed to plot the data from the beginning of the process, in real-time and then analyze its stability. Also, this method allows plotting different process variables on the same chart, as well as, apply Western Electric rules to study the point patterns and detect special causes [17, 30].

The four different cases for Q statistics from sample means, as well as the formulas to compute the Q statistics according to each situation are presented below.

Case I: when both, the mean μ and the variance σ^2 are known

$$Q_i(\overline{X}) = \frac{\sqrt{n_i(\overline{x}_i - \mu_0)}}{\sigma_0} \tag{25}$$

i= 1, 2, ...

Case II: μ is unknown, σ^2 is known

$$Q_i(\overline{X}) = \sqrt{\frac{n_i(n_1 + ... + n_{i-1})}{n_1 + ... + n_i}}(\frac{\overline{X_i} - \overline{\overline{X}}_{i-1}}{\sigma_0}) \qquad (26)$$

i= 2, 3, . . .

Case III: μ is known, σ^2 is unknown

$$Q_i(\overline{X}) = \Phi^{-}1[G_{n1} + ... + n_{i-i}(\frac{\sqrt{n_i}(\overline{X_i} - \mu_0)}{S_{p,i}}] \qquad (27)$$

i= 1, 2, . . .

Case IV: μ and σ^2 are unknown

$$Q_i(\overline{X}) = \Phi^{-1}\{G_{i-2}[(\frac{i-1}{i})^{1/2}(\frac{X_i - \overline{X}_{i-1}}{S_{i-1}})]\}, (i = 3, 4, ...) \qquad (28)$$

i= 2, 3, . . .

For cases III and IV Φ^{-1} denotes the inverse of the standard normal distribution, and G refers to the student-t distribution function.

The Q statistics values are plotted in the Q chart with a central line (CL) equal to 0 and, upper and lower control limits ±3 respectively [31]. Since the Q statistics are either standard normal variables with independent observations or approximately so, the resulting charts can all be constructed using the same scale and with the same control limits, thus simplifying charting administration, Additionally, when subgroups of sampling units vary in size, it is well understood that this situation is difficult to handle by traditional methods. By contrast, the control limits and interpretation of point patterns for Q charts are not affected by a varying sample size [32]. Quesenberry has demonstrated interesting debates that this method is particularly useful and with a lot of potential.

2.3.5 V Statistics

One of the main problems encountered in a short run production is that there are many different variables or measurements so that many different control charts are needed [33]. However, due to the few data collected this would not be possible.

Hence, standardized control charts that allow different variables to be plotted on the same chart are extremely useful in short runs, with standard scale simplify the control charting process in this manufacturing environment.

In this section of the literature review, this work addresses a multivariate SPC procedure for process dispersion based on individual measurements, The proposed chart plots standardized statistics for multiple variables on the same chart, and a brief discussion of the formulas needed to set up the chart for individual measurements and multivariate data is given below.

For individual measurements, assume that x_n=(x_{n1},x_{n2},...,x_{np}) where p is the quality characteristic measurements made on a part, and p x p is the covariance matrix associated with these observations, Assume that x_n came from a multivariate normal process where x_{nj} is the observation of the variate j at time n, and x_1,x_2,...,x_n are independently and identically distributed. Also, let $\overline{x}_n$=($\overline{x}_1$,$\overline{x}_2$,...,$\overline{x}_p$) represents the estimated mean vector from a sequence of $\overline{x}_1$,$\overline{x}_2$,...,$\overline{x}_n$ [33, 34].

In practice it is considered to transform the multivariate individual measurements to obtain standard normal V statistic for the four cases of μ and σ^2, known and unknown are below. Even though, it is recommended to use control charts for the unknown parameters for short runs, until enough data have been accumulated.

Case I: when both are known

$$T_n^2 = (x_i - \mu_0)\Sigma_0^{-1}(x_i - \mu_0) \tag{29}$$

and

$$V_i = \Phi^{-1}\{H_p(T_n^2)\} \tag{30}$$

n=1,2,...

Case II: μ is unknown, σ^2 is known

$$T_n^2 = (x_i - \overline{X}_{n-1})\Sigma^{-}1_0(x_i - \overline{X}_{n-1}) \tag{31}$$

and

$$V_n = \Phi^{-1}\{H_p[(\frac{n-1}{n})T_n^2]\} \tag{32}$$

n= 2, 3, ...

Case III: μ is known, σ^2 is unknown

$$T_n^2 = (x_i - \mu_0)S^-1_{0,n-1}(x_i - \mu_0) \tag{33}$$

where

$$S_{0,n} = \frac{1}{n}\sum_{i=1}^{n}(x_i - \mu_0)(x_i - \mu_0) \tag{34}$$

and

$$V_n = \Phi^{-1}\{F_{p,n\ -p}[(\frac{n-p}{p(n-1)})T_n^2]\} \tag{35}$$

n= p+1, p+2, ...

Case IV: μ and σ^2 are unknown

$$T_n^2 = (x_i - \overline{X}_{n-1})S^-1_{n-1}(x_i - \overline{X}_{n-1}) \tag{34}$$

where

$$S_n = \frac{1}{n-1}\sum_{i=1}^{n}(x_i - \overline{X}_n)(x_i - \overline{X}_n) \tag{37}$$

and

$$V_n = \Phi^{-1}\{F_{p,n\ -p}[(\frac{(n-1)(n-p-1)}{np(n-2)})T_n^2]\} \tag{38}$$

n= p+2,p+3, ...

Note that in the above formulas, p denotes the number of variables monitored simultaneously, while both $S_{0,n}$ and S_n represents the estimated covariance matrix. T^2 is based on the Hotelling T^2 classical statistic distribution. H is the chi-squared and F the Fisher-Snedecor, cumulative distribution functions. Moreover, the control limits parameters used to detect the presence of out of control signals are $\pm 3 sigma$, since the proposed chart is plotted from point having standardized normal scale.

2.4 Summary

Numerous SPC methods for short runs production have been proposed in the literature for control charts involving individual observations. Charts for Moving Range, EWMA, CUSUM, and Q charts are discussed in detail. These techniques provide a short run procedure based deviation from nominal values. As well as the V-statistics method was discussed, with the same approach as the previous techniques but it is aimed at multivariate process dispersion for a short runs production.

Chapter 3

Monitoring Control Charts for Short Production Processes

As mentioned previously from the literature review, most of the existing research aims to analyze statistical process control methods for low volume and multivariate processes employing numerical simulation. However, this thesis focuses on the performance of different short run control charts based on solid and realistic data collected from two different companies from UK. This chapter presents several low volume statistical methods to investigate how applicable are the concepts in industry. Also, the control charts are compared and analyzed. These control charts are based on the Q statistics, EWMA, CUSUM, and Individual methods. In the first section, we proposed control charts for low volume statistical process control based on historical data, and finally, we evaluate SPC for short runs based on mixed batches.

3.1 Control Charts for Low Volume Manufacturing Based on Historical Data

The control charts based on historical data have been proposed in this section of the chapter. The data have been collected from a part of Merck Co. company, which is a global pharmaceutical company located in Cramlington, Newcastle. The

MSD production facility produces billions of tablets every year. This is currently undertaken through a general batch manufacturing process following the flowchart below:

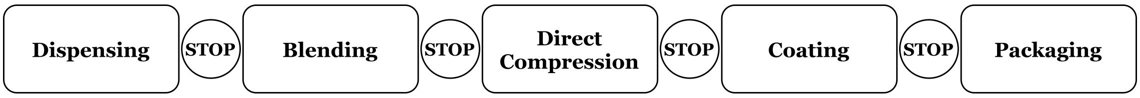


Figure 3.1: Batch Manufacturing Process

The dispensing, blending, compression, coating and packaging are the stages of the batch process, and the stop signs between steps mean a break in the production process. Once a stop occurs, the material is moving to the next process step until the batch production process is finished. Moreover, the batch process takes between five and seven days from dispensing to packaging. However, the company has recently invested in a continuous manufacturing process to achieve goals of increased batch size flexibility to meet goals of response to variable patient demand, for frequent product change over and greater assurance of product quality. The continuous process is more automated and efficient, allowing mostly the same process but without the stops between stages; speeding up production so much that tablets are produced in little over an hour. Also, the equipment for the continuous process is more modern; saving on factory floor space and the number of operators required.

Batch manufacturing process represented in figure 3.1 produces a high volume of data from which reliable SPC can be carried out upon ($\overline{x}$ charts and S charts). For the continuous process however, due to the intended frequent changeovers, data for only four batches was available, resulting in high volume statistical methods being unsuitable. New methods (as detailed below) suitable for such low volumes were researched and executed so reliable charts could be produced from such small samples. The analysis was carried out on only the API (Active Pharmaceutical Ingredient) concentration data of the processes. Out of all the data on the tablets, API concentration is perhaps the most important as it determines the effectiveness of the tablets produced.

3.1.1 Batch Manufacturing Process

MSD Cramlington have utilized the batch process for nearly a decade. As a result, there is extensive data available for analysis of this process. Data from two different batches have been collected, they are classified by their weight, 100 and 50 milligrams. Although this thesis brief focuses on low volume control, it was deemed important that control charts were drawn from the high volume batch process.

For a better understanding, the data collected (values based on API) at MSD from the batch process is used to develop the $\overline{x}$ and s chart as examples of traditional SPC methods.

The tables A.1 and A.2 in the appendix A shows the data from the tablet of 100mg and 50mg. To execute the $\overline{x}$ and S charts it is necessary to calculate the process parameters which are calculated with the equations 2, 3 and 4 explained in the literature review.

The control limits and central line of the $\overline{x}$ chart are calculated as:

For tablet of 100mg:

UCL=μ+3σ = 248.28+3(0.89514)
CL=μ = 248.28
LCL=μ-3σ = 248.28-3(0.89514)

For table of 50mg:

UCL=μ+3σ = 247.73+3(0.64592)
CL=μ = 247.73
LCL=μ-3σ = 247.73-3(0.64592)

and data are plotted against them in their respective control charts.

MSD is extremely confident in this process and permanently fixed control limits have been configured as a result. The Western Electric rules also plotted in these charts are not violated and therefore the batches can be deemed to be in control.

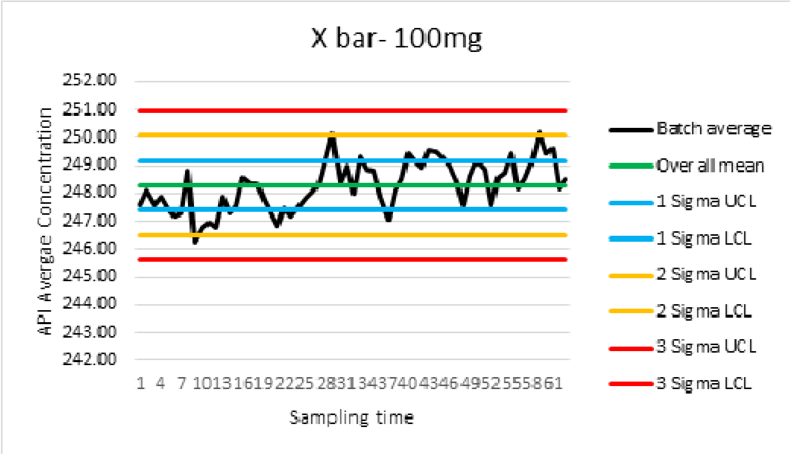


Figure 3.2: X bar Chart of Batch Manufacturing Process 100mg

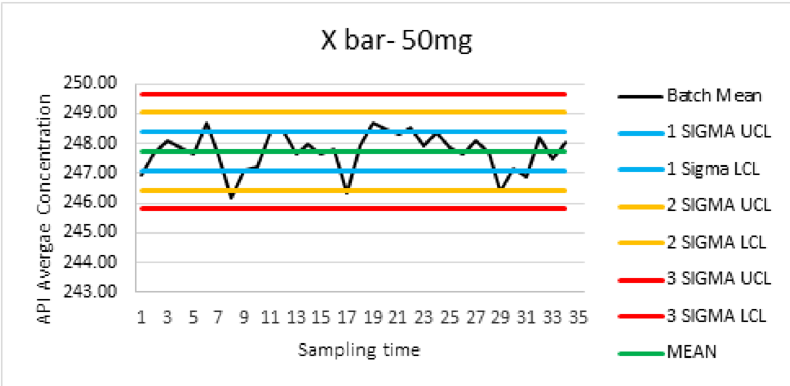


Figure 3.3: X bar Chart of Batch Manufacturing Process 50mg

Referring to the Figure 3.2, the mean of the active ingredient concentration appears to be increasing over time, this could forewarn that the process may become out of control in the near future. Similarly, the $\overline{x}$ charts for the 50mg batch processes, figure 3.3 is also in control according to the Western Electric rules.

MSD have carried out SPC using S and $\overline{x}$ charts successfully for many years, and therefore do not require a vast amount of data analysis using these methods. These charts confirm the results from the produced $\overline{x}$ charts. There is a data point in the S chart of the 100mg batch process (figure 3.4) that goes above the UCL line. From a statistical point of view, extreme values such as this can be accounted for by manufacturing deviations already known and investigated by MSD. The above traditional methods are suitable for the batch process; they showed a reliable statistical process control. Control charts were therefore easy to produce and often well

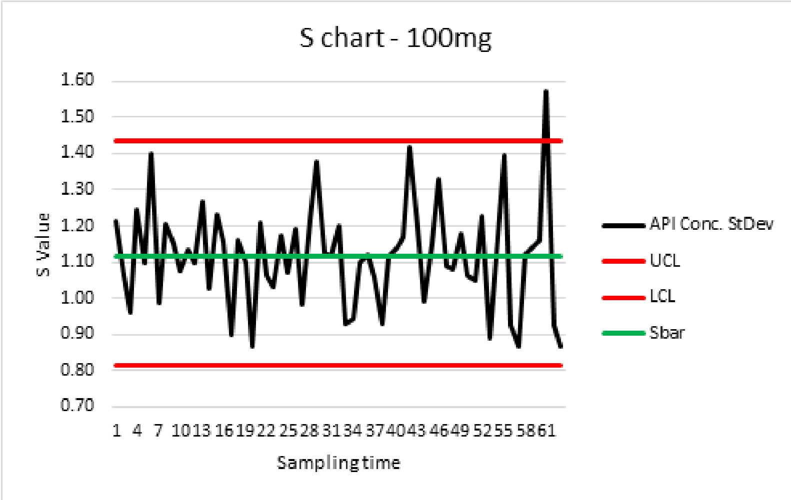


Figure 3.4: S Chart of Batch Manufacturing Process 100mg

within the operating limits.

3.1.2 Continuous Manufacturing Process

MSD has recently installed a more compact and flexible continuous direct compression line and manufactured four batches of material on this line in March 2019, which means that only four sets of composite samples are available. To analyze low volume data, it is necessary to implement control charts that more sensitives to small shifts than traditional control methods. Moreover, a major drawback of single Shewhart control charts is that they only use the information about the process contained in the last plotted point and ignore any information given by the entire sequence of points. This feature makes the Shewhart control chart relatively insensitive to small shifts in the process. Therefore, advanced control chart are developed, in order to analyze their effectiveness and performance. The data collected from batches A. B, C and D is situated in Appendix section, tables A.3 and A.4.

3.1.3 The Cumulative Sum (CUSUM)

To analyze low volume data, charts that are more sensitive than the $\overline{x}$ chart are required so that small shifts and trends can be detected. The CUSUM chart does this by incorporating current and previous data values from the process, this use of historical data means that a large number of data points are not necessary. Therefore, CUSUM chart is a very efficient control chart to detect small shifts in the process. It can be applied to a wide range of measured parameters (individual variable, sample average, range, and even defectives and count of defects).

In order to show the usefulness of the CUSUM chart to detect a small shift, the parameters have been calculated and are shown in the following tables 3.1, 3.2, 3.3 and, 3.4. Where Ci is the measured parameter at sampling time and is the cumulative sum of the deviations of sample values from the target, Ci+ and Ci- are calculated to build the two parts of the CUSUM chart. Ci+ and Ci- are called the High and Low CUSUM value and they are calculated using the equations 23 and 24. Somehow they accumulate all positive and negative data. Moreover, K is a factor that quantifies the efficiency of the control chart to detect an out-of-control situation. K is calculated as kσ where k is generally equal to 0.5. Finally, the decision interval H as the upper and lower control limits are estimated as $\pm h\sigma$, where h is a multiple value commonly equal to 5. Using the CUSUM, an out-of-control signal is quickly identified after sampling time.

The table above displays the 12 samples and the corresponding estimated parameters. As an example, for sample 1, 2 and 3 the process parameters are calculated below and were defined as equations 23 and 24. Considering that for C_0^+ and C_i^- is equal to 0.

According to equations 21, 22, 23, 24; To replace the values of Xi, μ, and σ on the equations, use the table A.5 in the appendix A.

For sample 1 we have

C_i=100.51-100.2831=0.2281

C_i^+=0

C_i^-=0

$H+$=+(5*.42)=2.099

$H-$=-(5*.42)=-2.099

For sample 2 we have

CUSUM BATCH A					
No	Ci	Ci+	Ci-	H+	H-
1	0.2281119	0	0	2.0996059	-2.0996059
2	0.63821157	0.200139	0	2.0996059	-2.0996059
3	0.32633143	0	0.10191955	2.0996059	-2.0996059
4	0.95466729	0.41837526	0	2.0996059	-2.0996059
5	1.08672567	0.34047305	0	2.0996059	-2.0996059
6	0.59573656	0	0.28102852	2.0996059	-2.0996059
7	0.12539719	0	0.5414073	2.0996059	-2.0996059
8	-0.32779365	0	0.78463755	2.0996059	-2.0996059
9	0.25232143	0.37015449	0	2.0996059	-2.0996059
10	-0.13432629	0	0.17668714	2.0996059	-2.0996059
11	0.08648793	0.01085364	0	2.0996059	-2.0996059
12	7.1054E-14	0	0	2.0996059	-2.0996059

Table 3.1: Parameters for CUSUM Chart in Batch A

C_i=(100.69-100.2831)+0.2281=0.6382

C_i^+=100.69-(100.2831+(0.5*0.42))+0=0.200139

C_i^-=(100.2831+(0.5*0.42))-100.69+0=0

$H+$=+(5*.42)=2.099

$H-$=-(5*.42)=-2.099

For sample 3 we have

C_i=99.97-100.2831=0.3263

C_i^+=99.97-(100.2831+(0.5*0.42))+0.200139=0

C_i^-=(100.2831+(0.5*0.42))-99.97+0=0.1019

$H+$=+(5*.42)=2.099

$H-$=-(5*.42)=-2.099

CUSUM BATCH B					
No	Ci	Ci+	Ci-	H+	H-
1	-0.00921468	0	0	2.82071854	-2.82071854
2	-0.04703115	0	0	2.82071854	-2.82071854
3	0.5169216	0.2818809	0	2.82071854	-2.82071854
4	-0.897391	0	1.13224076	2.82071854	-2.82071854
5	-0.6448823	0	0.5976602	2.82071854	-2.82071854
6	-0.29441907	0.06839138	0	2.82071854	-2.82071854
7	-0.08795533	0	0	2.82071854	-2.82071854
8	-0.50560464	0	0.13557745	2.82071854	-2.82071854
9	-0.8043747	0	0.15227566	2.82071854	-2.82071854
10	-0.5543832	0	0	2.82071854	-2.82071854
11	4.2633E-14	0.27231135	0	2.82071854	-2.82071854

Table 3.2: Parameters for CUSUM Chart in Batch B

CUSUM BATCH C					
No	Ci	Ci+	Ci-	H+	H-
1	0.28973352	0	0	2.01684984	-2.01684984
2	0.56605865	0.07464	0	2.01684984	-2.01684984
3	0.8589747	0.165871	0	2.01684984	-2.01684984
4	0.43384979	0	0.22343993	2.01684984	-2.01684984
5	0.18412222	0	0.27148251	2.01684984	-2.01684984
6	-0.10109849	0	0.35501824	2.01684984	-2.01684984
7	0.07006721	0	0	2.01684984	-2.01684984
8	-0.50953439	0	0.37791661	2.01684984	-2.01684984
9	-0.53690738	0	0.20360462	2.01684984	-2.01684984
10	0.25423492	0.58945731	0	2.01684984	-2.01684984
11	1.279E-13	0.13353741	0.05254993	2.01684984	-2.01684984

Table 3.3: Parameters for CUSUM Chart in Batch C

CUSUM BATCH D					
No	Ci	Ci+	Ci-	H+	H-
1	0.88145351	0	0	3.88549742	-3.88549742
2	0.59963456	0	0	3.88549742	-3.88549742
3	0.60480985	0	0	3.88549742	-3.88549742
4	0.42754941	0	0	3.88549742	-3.88549742
5	0.27010754	0	0	3.88549742	-3.88549742
6	1.52579617	0.86713889	0	3.88549742	-3.88549742
7	1.35466807	0.30746105	0	3.88549742	-3.88549742
8	0.42448819	0	0.54163014	3.88549742	-3.88549742
9	1.36476622	0.55172829	0	3.88549742	-3.88549742
10	0.52231711	0	0.45389937	3.88549742	-3.88549742
11	1.13539458	0.22452773	0	3.88549742	-3.88549742
12	-1.7053E-13	0	0.74684484	3.88549742	-3.88549742

Table 3.4: Parameters for CUSUM Chart in Batch D

Once the process parameters have been estimated, control charts have been constructed according to sampling time 1 to 12, and they are shown below in figure 3.5 to 3.8.

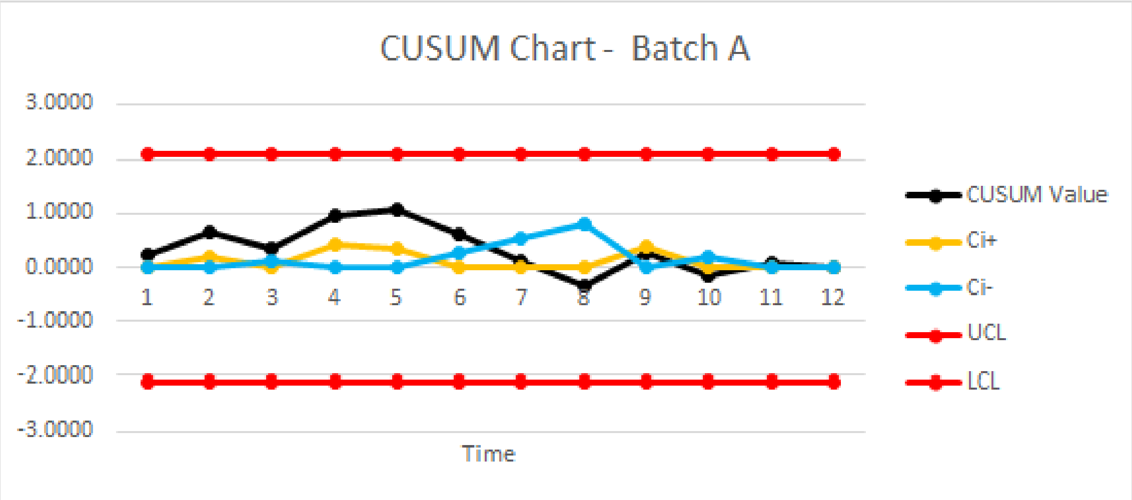


Figure 3.5: CUSUM Chart for Batch A

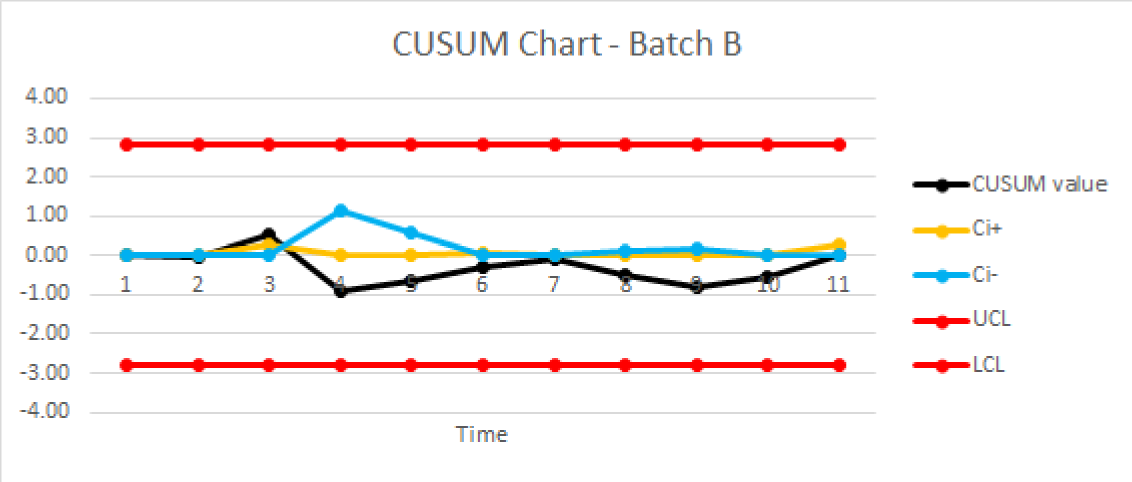


Figure 3.6: CUSUM Chart for Batch B

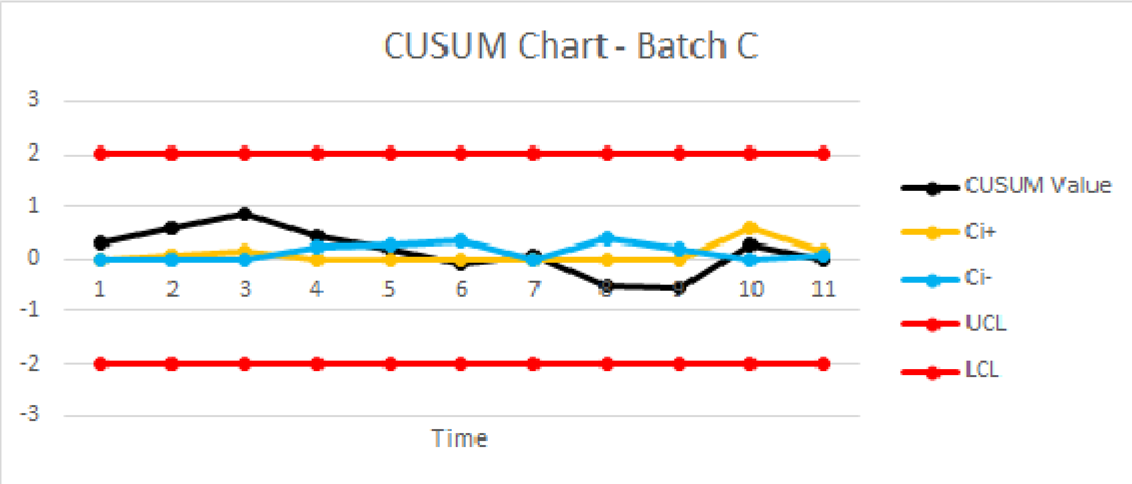


Figure 3.7: CUSUM Chart for Batch C

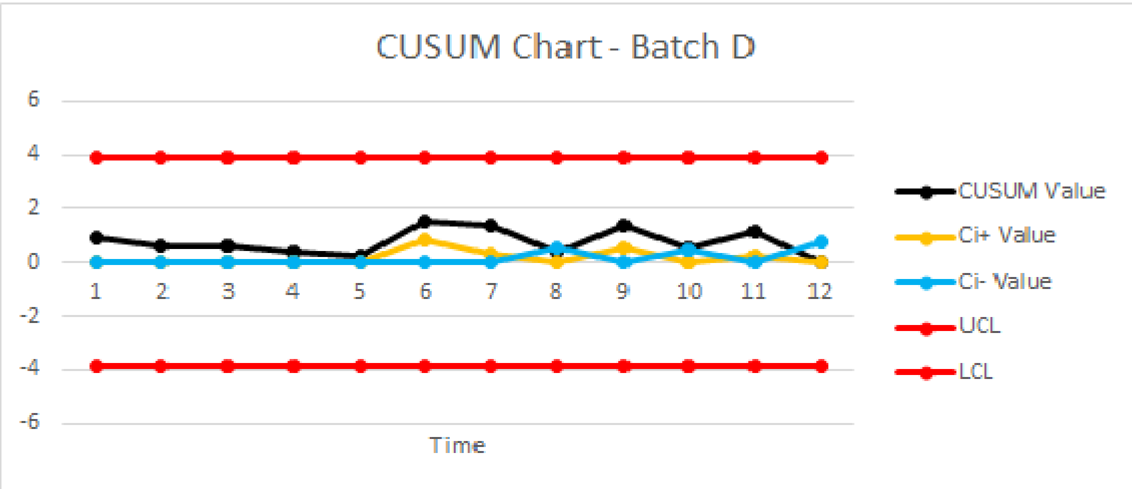


Figure 3.8: CUSUM Chart for Batch D

CUSUM chart for the continuous batch A, figure 3.5 it can be seen that the CUSUM value sits comfortably and stabilizes between the control limits or decision interval. This could be attributed to the machine reaching a steady state over time. Similar results can be seen from the in-batch data for B, C and D.

3.1.4 Exponentially Weighted Moving Average (EWMA)

The Exponentially Weighted Moving Average (or EWMA) is also a good alternative control chart when we are interested in detecting small shifts. The performance of the EWMA is approximately equivalent to that of the CUSUM and easier to set up and operate.

The following tables show the process parameters to build the EWMA control chart for batches A, B, C, and D.

BATCH A			
No	Zi EWMA value	UCL	LCL
1	100.306	100.409	100.157
2	100.345	100.453	100.114
3	100.307	100.481	100.085
4	100.368	100.501	100.065
5	100.372	100.516	100.050
6	100.314	100.528	100.038
7	100.264	100.537	100.029
8	100.221	100.544	100.022
9	100.285	100.550	100.017
10	100.246	100.554	100.012
11	100.272	100.557	100.009
12	100.264	100.560	100.006

BATCH B			
No	Zi EWMA value	UCL	LCL
1	99.881	100.080	99.683
2	99.877	100.148	99.615
3	99.934	100.193	99.570
4	99.787	100.225	99.538
5	99.822	100.249	99.515
6	99.863	100.267	99.496
7	99.885	100.281	99.482
8	99.843	100.292	99.471
9	99.817	100.301	99.462
10	99.849	100.308	99.455
11	99.907	100.314	99.450

Table 3.5: Parameters for EWMA Chart in Batch A and B

The table above displays the 12 samples and the corresponding estimated parameters. As an example, for sample 1, 2 and 3 the process parameters are calculated below and were defined as equations 17, 19, and 20. To replace the values of Xi, μ, and σ on the equations, use the table A.5 in the appendix A. Also, the process parameter λ, which determines how old or recent is the data considered to calculated the Z value, takes the recommended value of 0.1.

According to equation 17; For sample 1, 2, and 3 we have

$$Z_1 = 0.1 * 100.5111 + (1 - 0.1) * 100.2831 = 100.306$$
$$Z_2 = 0.1 * 100.6932 + (1 - 0.1) * 100.306 = 100.345$$
$$Z_3 = 0.1 * 99.9712 + (1 - 0.1) * 100.345 = 100.307$$

According to equation 19; For sample 1, 2, and 3 we have

$$UCL = 100.2831 + 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*1}]} = 100.409$$

$$UCL = 100.2831 + 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*2}]} = 100.453$$

$$UCL = 100.2831 + 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*3}]} = 100.481$$

According to equation 20; For sample 1, 2, and 3 we have

$$LCL = 100.2831 - 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*1}]} = 100.157$$

$$LCL = 100.2831 - 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*2}]} = 100.114$$

$$LCL = 100.2831 - 3 * 0.42\sqrt{\tfrac{0.1}{(2-0.1)}[1 - (1 - 0.1)^{2*3}]} = 100.085$$

The same equations are used to estimate the parameters of following samples and batches.

BATCH C				BATCH D			
No	Zi EWMA value	UCL	LCL	No	Zi EWMA value	UCL	LCL
1	98.909	99.158	98.602	1	99.538	99.682	99.216
2	98.934	99.254	98.506	2	99.617	99.763	99.136
3	98.958	99.317	98.444	3	99.572	99.815	99.083
4	98.907	99.361	98.399	4	99.560	99.853	99.046
5	98.880	99.395	98.365	5	99.531	99.881	99.018
6	98.851	99.420	98.340	6	99.507	99.902	98.996
7	98.871	99.440	98.320	7	99.627	99.919	98.980
8	98.814	99.456	98.305	8	99.592	99.932	98.967
9	98.818	99.468	98.292	9	99.485	99.942	98.956
10	98.903	99.478	98.282	10	99.575	99.951	98.948
11	98.876	99.486	98.275	11	99.479	99.957	98.942
				12	99.537	99.962	98.936

Table 3.6: Parameters for EWMA Chart in Batch C and D

The corresponding control charts have also been constructed as shown in figures 3.9 to 3.12

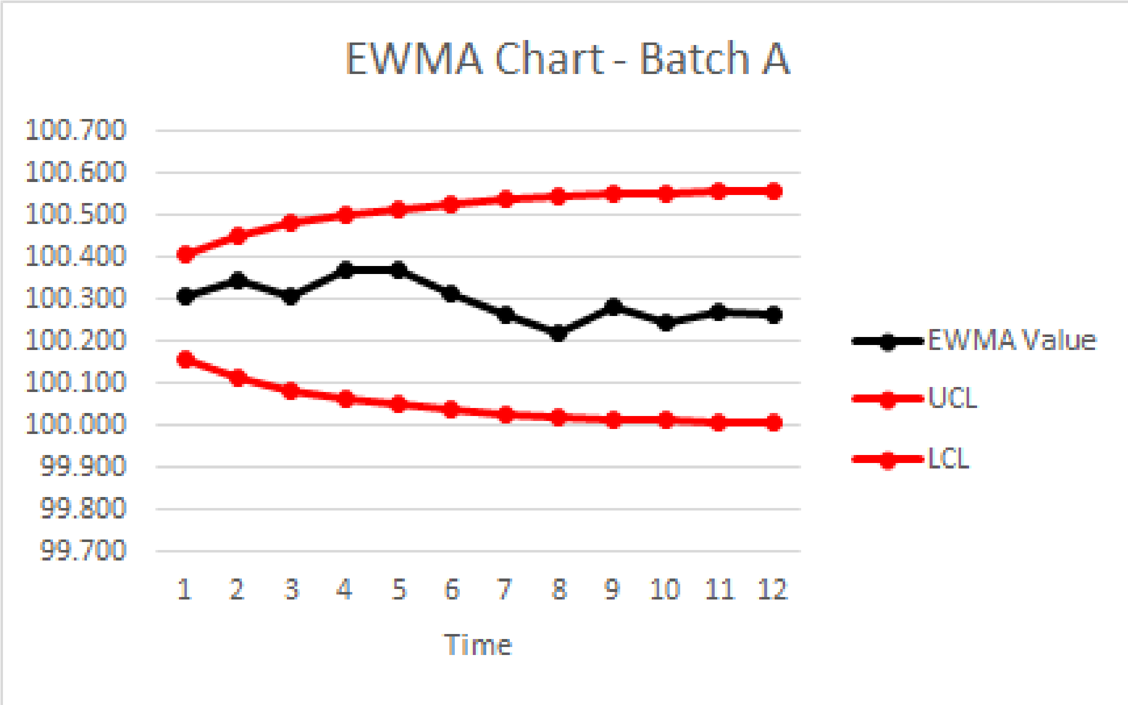


Figure 3.9: EWMA Chart for Batch A

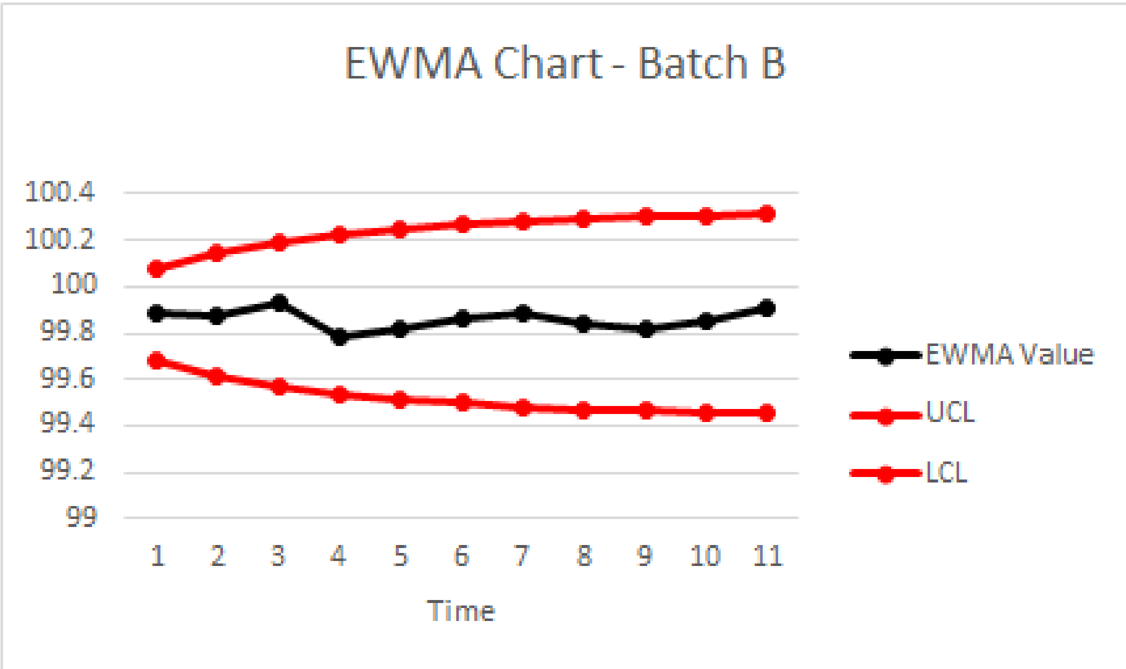


Figure 3.10: EWMA Chart for Batch B

The resulting EWMA charts have been very similar to CUSUM charts, the process is observed in control and the EWMA value is constant through time.

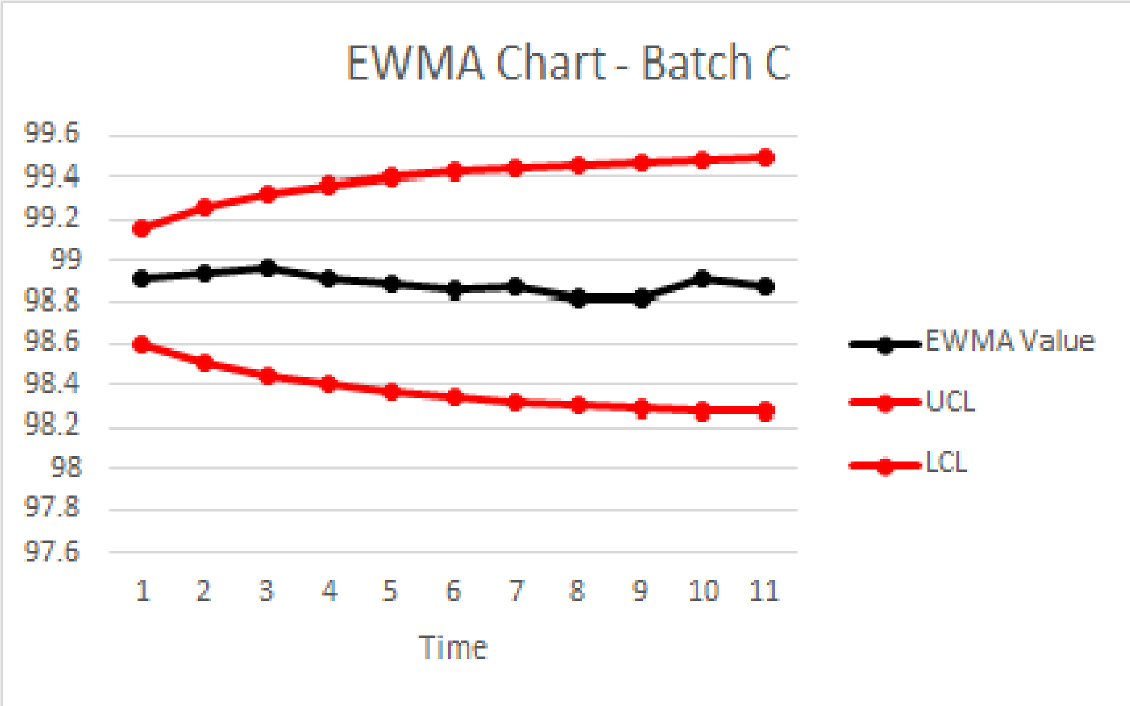


Figure 3.11: EWMA Chart for Batch C

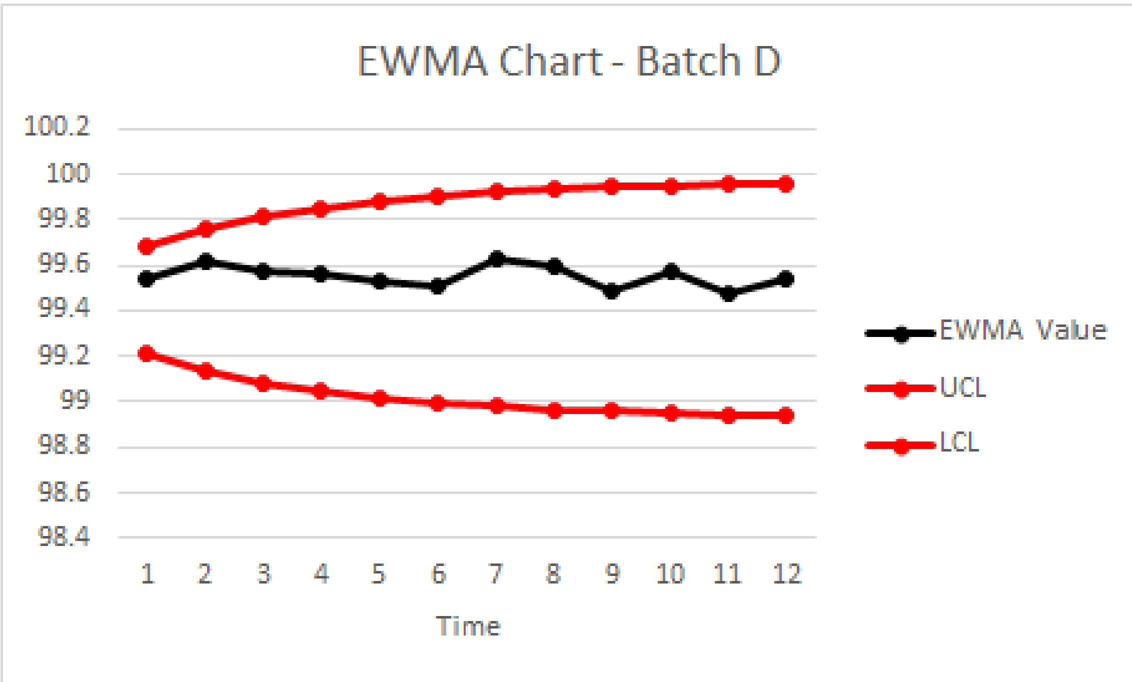


Figure 3.12: EWMA Chart for Batch D

3.1.5 Q Charts

Q charts enable to being monitoring the process with the first production samples and are the final method used in continuous process analysis. Q charts require little data; just the mean and standard deviation of the small groups. They are used during start up to detect changes in the process parameters because they do not require rich preliminary data.

The parameter to build the Q charts, are shown in the tables below

BATCH A			
No	Q value	UCL	LCL
1	0.543225521	1.2597635	-1.259764
2	0.976611054	1.2597635	-1.259764
3	-0.742711133	1.2597635	-1.259764
4	1.496318555	1.2597635	-1.259764
5	0.31448373	1.2597635	-1.259764
6	-1.169241118	1.2597635	-1.259764
7	-1.120065835	1.2597635	-1.259764
8	-1.079228339	1.2597635	-1.259764
9	1.381485641	1.2597635	-1.259764
10	-0.920762618	1.2597635	-1.259764
11	0.525846843	1.2597635	-1.259764
12	-0.205962302	1.2597635	-1.259764

BATCH B			
No	Q value	UCL	LCL
1	-0.013943086	1.982635	-1.98263
2	-0.057221531	1.982635	-1.98263
3	0.853338254	1.982635	-1.98263
4	-2.140049917	1.982635	-1.98263
5	0.382080472	1.982635	-1.98263
6	0.530299172	1.982635	-1.98263
7	0.312408095	1.982635	-1.98263
8	-0.631960968	1.982635	-1.98263
9	-0.45208028	1.982635	-1.98263
10	0.378271594	1.982635	-1.98263

Table 3.7: Parameters for Q Chart in Batch A and B

The table above displays the 12 samples and the corresponding estimated parameters. As an example, for sample 1, 2 and 3 the process parameters are calculated below by equation 25 for Q value. To replace the values of Xi, μ, and σ on the equations, use the table A.5 in the appendix A.

According to equation 25 $Q_i(\overline{X}) = \frac{\sqrt{n_i(\overline{x}_i - \mu_0)}}{\sigma_0}$ the Q values for sample 1, 2 and 3 are

$$Q_1(\overline{X}) = \frac{\sqrt{1(100.5111 - 100.2831)}}{0.42} = 0.5432$$

$$Q_2(\overline{X}) = \frac{\sqrt{1(100.6931 - 100.2831)}}{0.42} = 0.9766$$

$$Q_3(\overline{X}) = \frac{\sqrt{1(99.9711 - 100.2831)}}{0.42} = -0.7427$$

To estimate the control limits, use the following formulas

UCL=+3σ=+3*0.42=1.26

UCL=-3σ=-3*0.42=-1.26

The same formulas are used to estimate the parameters of all the batches.

BATCH C			
No	Q value	UCL	LCL
1	0.31269341	2.7797214	-2.779721
2	0.298222479	2.7797214	-2.779721
3	0.316128145	2.7797214	-2.779721
4	-0.458813876	2.7797214	-2.779721
5	-0.269517199	2.7797214	-2.779721
6	-0.307822981	2.7797214	-2.779721
7	0.184729696	2.7797214	-2.779721
8	-0.625532043	2.7797214	-2.779721
9	-0.029542161	2.7797214	-2.779721
10	0.85383626	2.7797214	-2.779721
11	-0.274381731	2.7797214	-2.779721

BATCH D			
No	Q value	UCL	LCL
1	0.56878771	-3.779291	3.779291
2	0.224766377	-3.779291	3.779291
3	1.589563921	-3.779291	3.779291
4	-0.187777314	-3.779291	3.779291
5	0.75036289	-3.779291	3.779291
6	1.928143322	-3.779291	3.779291
7	1.889107994	-3.779291	3.779291
8	1.856691199	-3.779291	3.779291
9	-0.096622974	-3.779291	3.779291
10	1.730901148	-3.779291	3.779291
11	0.5825829	-3.779291	3.779291
12	1.163492827	-3.779291	3.779291

Table 3.8: Parameters for Q Chart in Batch C and D

To analyze the behavior of this process, the Q charts have been developed, which are shown below

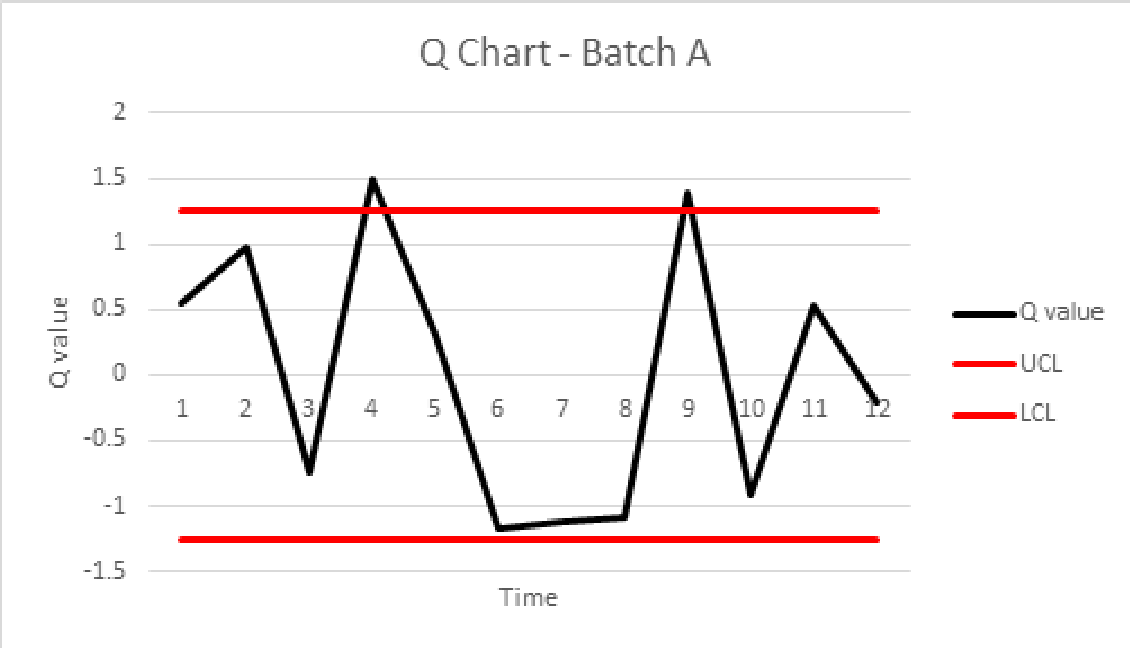


Figure 3.13: Q Chart for Batch A

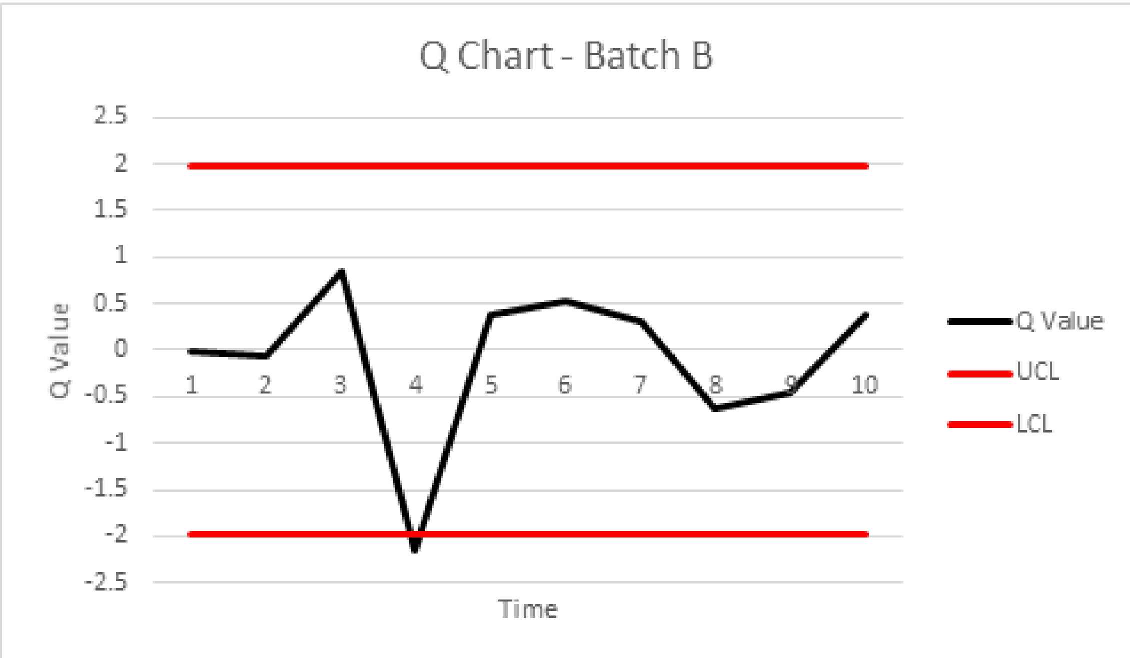


Figure 3.14: Q Chart for Batch B

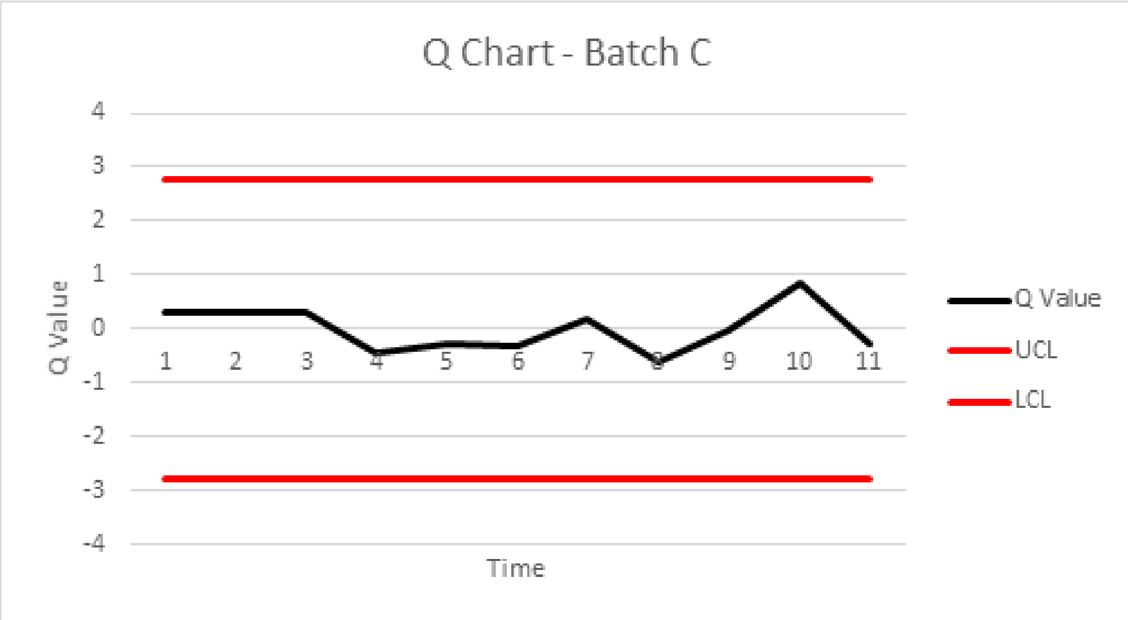


Figure 3.15: Q Chart for Batch C

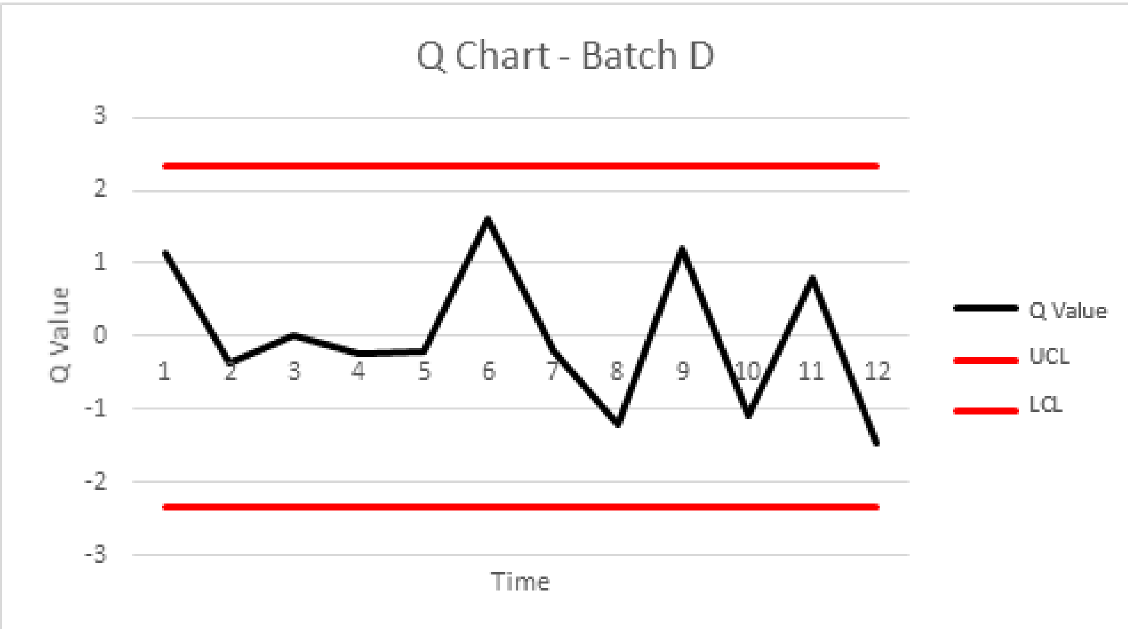


Figure 3.16: Q Chart for Batch D

The results of these charts appear to be very different compared to CUSUM and EWMA. As shown in batches A and B, they amplify variation too much, and risk false warnings being triggered while missing slow changes in the mean over time. It seems that Q chart cannot detect the shift of this particular process mean immediately, the plotted data will quickly become steady at a new level and the chart tends to miss the shift.

Considering the control charts which shows the continuous manufacturing process and batch to batch graphs. It can be seen that even with a few data points, the CUSUM chart can provide a steady and reliable indication of control with minimal noise interference. In contrast, the EWMA and Q charts provide less useful information. Although EWMA shows that the process is in control, it is important to note that the EWMA chart limits have not yet approached their steady state value by the end of the data, this can be attributed to the size of the data set. The Q chart is affected similarly; the size of the data set results in points one and three dictating the position of the control lines. However, in this case Q charts show an out of control process.

3.2 SPC for Short Runs Based on Mixed Batches and Multivariate Processes

Statistical Process Control for Short Runs Based on Mixed Batches and Multivariate Processes refers to a set of advanced techniques to monitor and control the operating performance of batch and continuous processes.

Nowadays, there is an increasing need for versatility and flexibility in highly efficient systems, and with it a need for the user to be able to plot similar characteristics of different parts, or different characteristics of a part, on a single control chart.

In low volume process scenarios with many part numbers, different target values and sample sizes, production runs are often too small to generate enough data to apply standard control charts. For this reason, this section focuses on SPC applies in mixed batches and multivariate processes, with the approach to plot the dispersion of the process, subtracting the difference from nominal and the target value. Thus, the data obtained can be plotted in the processing order on a single chart.

The Workshop situated in the Durham University Engineering Department was taken as a case study for the analysis of both cases, due to the workshop manufacture different products on the same machine. In the next sections, the application of different SPC methods will be developed. Firstly, they will be implemented in scenarios where it is necessary to analyze the process of same characteristic but different target values and batches. Secondly, an alternative method will be shown to analyze different variables of the same part on a single control chart.

3.2.1 SPC for Short Runs Based on Mixed Batches

Mixed batches belongs to the case study where different parts are produced by the same machine, considering the same characteristic to analyze for all the parts, but with different target values.

Table 3.9 shows the data collected for this case, 23 batches, each with different target value and number of samples. SPC methods such as individual X, Moving Range, Moving Average, and Q charts have been adopted in order to plot, monitor and control similar process and characteristic of different items, on the same control chart.

Batch	Target	X1	X2	X3	X4	X5	X6	X7	X8
1	166	167.00	166.73	166.79	166.84	167.10			
2	152.55	153.48	153.44	152.87	153.24	153.29	153.18	152.96	153.21
3	170	170.27	170.21	169.99	169.82				
4	160	160.25	160.24	160.08	159.79	160.37			
5	177.5	177.33	176.89	176.77	177.01	177.93			
6	167.5	168.15	168.42	168.13					
7	177.5	177.52	177.46	177.44	177.55				
8	167.5	168.12	168.42	168.48	168.55				
9	80	79.34	80.15	80.16					
10	125	125.17	125.29						
11	380	380.11	380.08	380.05	380.08	380.06	379.93		
12	500	499.76	499.95	499.97	499.95				
13	10	10.05							
14	318	317.96	318.00	318.11	318.00				
15	110	110.05	109.96						
16	357	357.45	357.00	356.99	357.47	357.00	359.98		
17	90	90.07	90.07						
18	103	103.07							
19	83	83.01	83.05						
20	61	61.04							
21	411	410.63							
22	14	14.06							
23	40	40.1	39.97						

Table 3.9: Data Collected from the Workshop in the Durham University Engineering Department Based on the Study Case of Mixed Batches

3.2.2 Individual X Bar Chart

The first method is the Individual X chart, whilst some batches produced in the Engineering Workshop featured up to 8 samples, the batch size is inconsistent with a minimum group size of 1. To develop this method, it is necessary that the sub group size of the data is strictly 1, and continuous. To ensure that the data was continuous given each batch had different specification target values, each measurement error from its target must be plotted. This meant that 76 separate data points were plotted across the Individual X chart.

In the individuals plot, each point is based on a single measurement. Plotting deviations from the target value.

No	Part	Target X	X	Individual X
1	1	166	167	1
2	1	166	166.73	0.73
3	1	166	166.79	0.79
4	1	166	166.84	0.84
5	1	166	167.10	1.10
6	2	152.55	153.48	0.93
7	2	152.55	153.44	0.89
8	2	152.55	152.87	0.32
9	2	152.55	153.24	0.69
10	2	152.55	153.29	0.74
11	2	152.55	153.18	0.63
12	2	152.55	152.96	0.41
13	2	152.55	153.21	0.66
14	3	170	170.27	0.27
15	3	170	170.21	0.21

Table 3.10: Individual X Values from Engineering Workshop Data

Table 3.10 shows the resulting Individual X values of the first 15 consecutive samples taken from the machine, that have been calculated using the following formula

Individual X= X-T

Where X is the sample taken and T the target value

As an example, for sample 1 and 2 we have

Individual X1= 167 - 166 = 1

Individual X2= 166.73 - 166 = 0.73

Moreover, to construct the control chart is necessary to calculate the control limits and central line following the formulas below

CL=0

UCL= + 2.66 * 2

LCL= - 2.66 * 2

where 2.66 is the value from constant d2, the constant takes into account the 3 used to calculate the upper and lower control limit. d2=3/1.128. Also, 2 is based on moving range of 2 for this case, being 5.32 and -5.32 the upper and lower control limits respectively.

The control chart for Individual X values is shown in figure 3.17, the control chart displays over time the individual measurements. This graph shows a process in control, no point on the chart is above the control limits. However, this chart breaks down in sample 66, it is advisable to analyze the events in the workshop at the time to investigate potential root causes for this outlier, also compare the process with the following methods.

3.2.3 Moving Range

In the moving range chart, the absolute value of the difference between each two consecutive individual measurements have been plotted. In fact, this and the methods developed below will depend on the individual measurements calculated in the previous method, since the statistical process control approach in this case is focused on monitoring the process dispersion rather than the mean values.

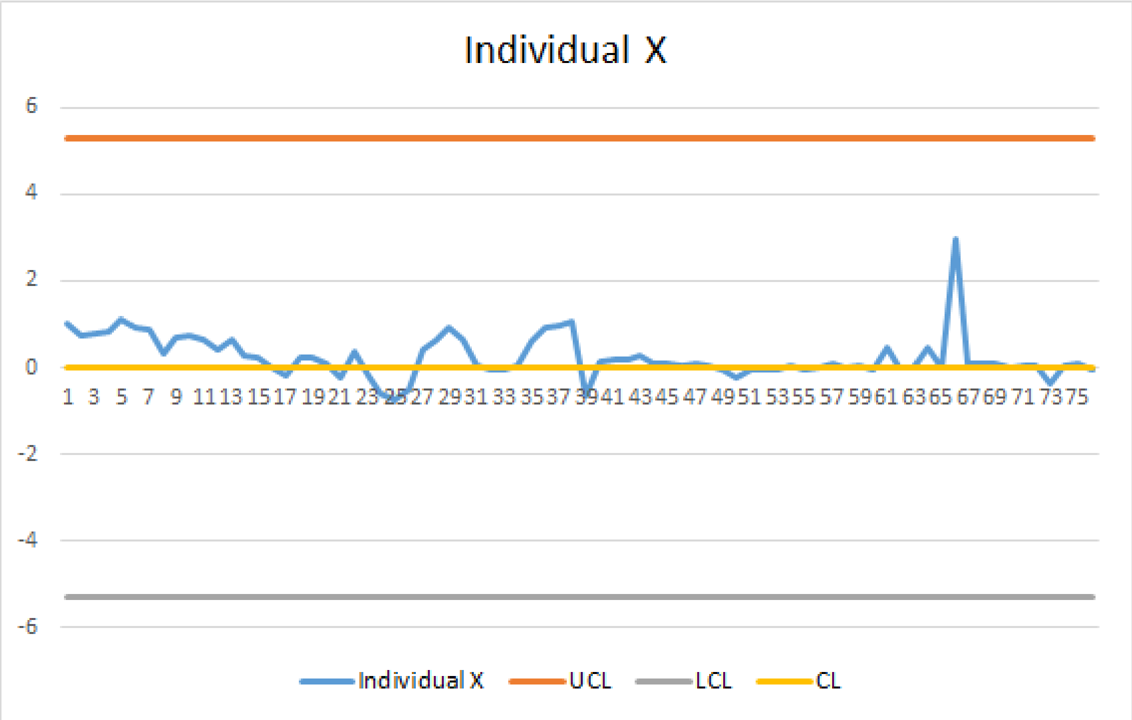


Figure 3.17: Individual X Chart for Engineering Workshop Data

No	Individual X	Moving Range
1	1	
2	0.73	0.27
3	0.79	0.06
4	0.84	0.05
5	1.10	0.26
6	0.93	0.17
7	0.89	0.04
8	0.32	0.57
9	0.69	0.37
10	0.74	0.05
11	0.63	0.11
12	0.41	0.22
13	0.66	0.25
14	0.27	0.39
15	0.21	0.06

Table 3.11: Moving Range Values from Engineering Workshop Data

The table above displays the first 15 samples and the corresponding moving range values

As an example, for sample 1 and 2 we have

MR_1=ABS(X_1 - X_2) = ABS(1 - 0.73) = 0.27

MR_2=ABS(X_2 - X_3) = ABS(0.73 - 0.79) = 0.06

Moreover, the process parameters are calculated below and were defined as equations 14, 15, and 16:

UCL=$\overline{X} + 3\frac{\overline{MR}}{1.128} = 0.25 + 3(\frac{0.30}{1.128}) = 1.05$

CL=$\overline{X} = 0.25$

LCL=$\overline{X} + 3\frac{\overline{MR}}{1.128} = 0.25 - 3(\frac{0.30}{1.128}) = -0.55$

where $\overline{x}$ is the average of all the individuals and $\overline{MR}$ is the average of all the moving ranges of two observations, and d2 is a constant value equal to 1.128 for n=2.

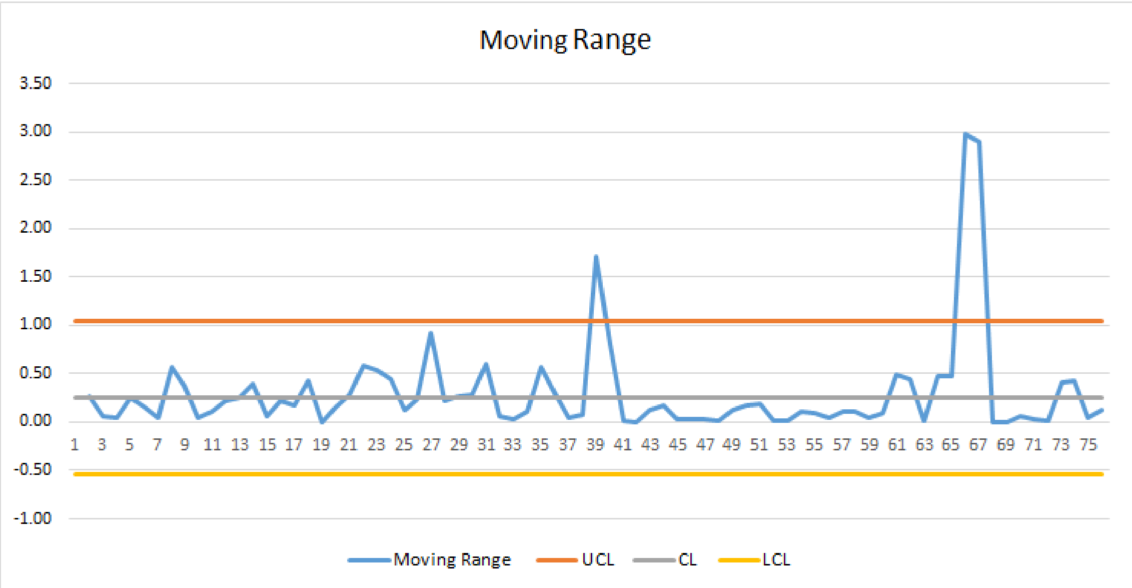


Figure 3.18: Moving Range Chart for Engineering Workshop Data

We note that three points, those from sampling time 39, 66, and 67, plot above the upper control limit, so the process is not in control. These points must be investigated to see whether an assignable cause can be determined. Analysis of the data from sampling 39 and 67 indicates that new part numbers were put into production during that period. The introduction of new parts sometimes causes irregular production performance, and it is reasonable to believe that it has occurred here. Furthermore, during the period in which sampling 66 was obtained requires a deeper analysis to conclude the cause.

3.2.4 Q statistic

The Q chart technique is a statistical process control method that permits the monitoring of various components. This method involves the transformation of the mean to sequences of independent process dispersion values. The Q statistic can be plotted to the standard normal control chart with center line at zero and control limits at ± 3. It is also possible for Q chart to plot different parts in one chart because of its standardized control limits.

It is mainly the case IV when both μ and σ are unknown for short production runs, since most of the time the process mean and standard deviation are not known in advance. In this case, the development of Q chart is focus on the study of Q statistic of Case IV.

The data in the table 3.12 below shows the first 15 of the 73 samples collected and the resulting Q values to be plotted in the control chart

The Q statistic values were calculated using the Excel code:

”=INV.NORM.STAND(DIST.T.N(((COUNT(Xi:Xn))/ (COUNT(Xi:Xn)+1))* ((E5-AVERAGE(Xi:Xn)/STDEV.P(Xi:Xn))),COUNT(Xi:Xn)-1,TRUE))”

Which is based in the formula 26 explained in the literature review,

No	Individual X	Q statistic
1	1	
2	0.73	
3	0.79	-1.3765714
4	0.84	-2.0357999
5	1.10	-2.5576671
6	0.93	-2.5813969
7	0.89	-2.9547799
8	0.32	-3.4013713
9	0.69	-2.1645319
10	0.74	-2.2526265
11	0.63	-2.4509275
12	0.41	-2.617574
13	0.66	-2.2524615
14	0.27	-2.5795228
15	0.21	-2.3035828

Table 3.12: Q statistic from Engineering Workshop Data

The Q chart shows one point outside the lower control limit, so the process is not in control. Moreover, it is observed that the first 28 samples are close to the lower control limit, with an upward trend until the process stabilizes. However, there is a sudden change in sample 66, as well as it has also been observed in the previous methods. Although, in this case the upper control limit is above the Q statistic value of sample 66. In this case it is necessary to analyze the process parameters.

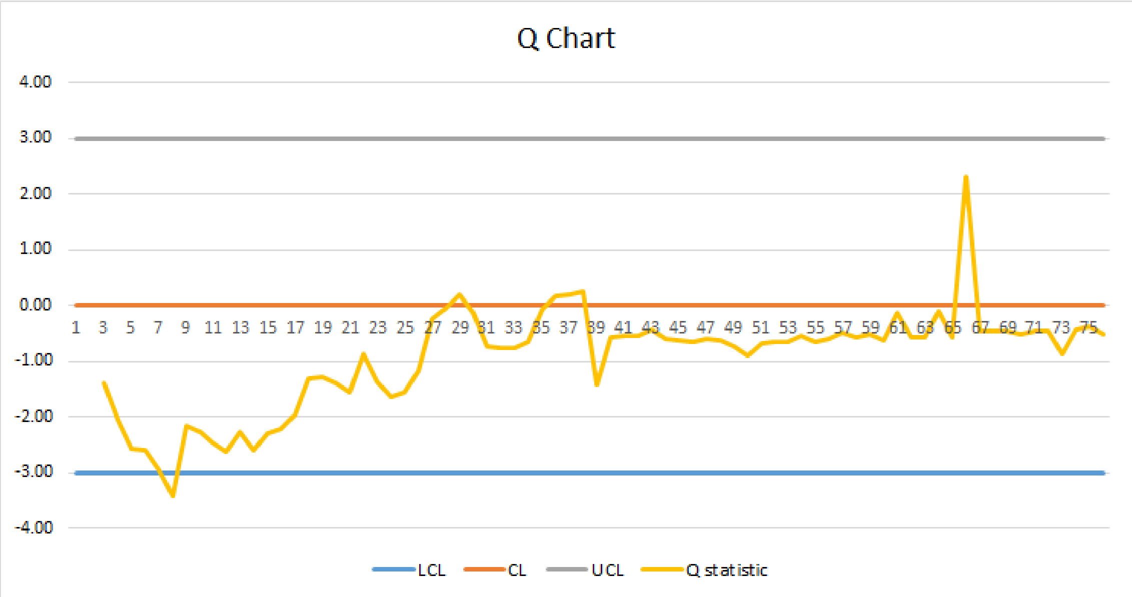


Figure 3.19: Q Chart for Engineering Workshop Data

3.2.5 Statistical Process Control for Short Runs Based on Multivariate Processes

SPC for multivariate processes is focused on process monitoring in which several related variables are involved. For this case we have considered the data collected from the workshop, that involves multiple characteristics with different specified nominal values, as well as inconsistent sample sizes. The data is shown in the table 3.13, however, only the first 17 samples of 76 are provided in this section (a a complete dataset is provided in table 3.9). It shows the variables length and diameter, the samples collected from each part, and their target values.

No	Part	Length		Diameter	
		Target	X1	Target	X2
1	1	166	167	16	16.00
2	1	166	166.73	16	16.08
3	1	166	166.79	16	16.06
4	1	166	166.84	16	15.99
5	1	166	167.10	16	16.06
6	2	152.55	153.48	15	14.93
7	2	152.55	153.44	15	14.89
8	2	152.55	152.87	15	14.95
9	2	152.55	153.24	15	14.85
10	2	152.55	153.29	15	14.92
11	2	152.55	153.18	15	14.92
12	2	152.55	152.96	15	14.90
13	2	152.55	153.21	15	15.02
14	3	170	170.27	20	20.06
15	3	170	170.21	20	20.12
16	3	170	169.99	20	20.00
17	3	170	169.82	20	19.95

Table 3.13: Data Collected from the Workshop in the Durham University Engineering Department Based on the Study Case of a Multivariate Process

3.2.6 V Statistics

V statistic is an extension to the Hotelling T_2 classical method. V is a standardize statistic value representing a combination of a set of variables. As is explained in the literature review, there are four cases in which this method can be considered, when the parameters are known or unknown.

The case of both unknown parameters is most important, as it reflects the actual problem faced in short runs. As mentioned before, the use of the equations 35,34, and 37 is necessary.

The data in table 3.14 below shows the first 15 of the 73 samples collected and the resulting values of T^2 and S_n, which are necessary to finally obtain the V statistic value and construct the control chart.

To calculate T^2, S_n, and V statistic, the values are substituted in the equations mentioned above, also explained in section 2.3.5, for sample 1 and 2

These equations are calculated using Excel

$S_2 = \frac{1}{2-1}(-0.005 + 0) = 0.0029$

$T_3^2 = (0.79 - 0.863)(0.0029^{)-1}(0.06 - 0.0375) = -0.4986$

$V_3 = \phi^{-1}[\frac{(3-1)(3-2-1)}{3(2)(3-2)}(-0.498)] = 0$

$S_3 = \frac{1}{3-1}(-0.00064 - 0.0058 + 0) = 0.0043$

$T_4^2 = (0.84 - 0.83)(0.0043)^{-1}(0.01 - 0.043) = 0.0043$

$V_4 = \phi^{-1}[\frac{(4-1)(4-2-1)}{4(2)(4-2)})(0.0043)] = -0.375$

The data necessary to be plotted on the control chart have been calculated applying the above formulas to all samples. Estimating the values for T^2 and S_n, in order to calculate V statistic values. Also the standardized three sigma control limits are plotted in the chart.

No	Individual X1	Individual X2	Sn	T^2	V Statistic
1	1.00	-0.01			
2	0.73	0.08	#¡DIV/0!	#¡DIV/0!	
3	0.79	0.06	344.332855	-0.49864499	#¡DIV/0!
4	0.84	-0.01	232.487682	0.00435316	-0.37574459
5	1.10	0.06	206.993621	1.53239965	0.25218473
6	0.93	-0.07	733.816847	-3.27456256	-0.71497593
7	0.89	-0.11	249.880753	0.20234685	0.05601248
8	0.32	-0.05	277.292194	8.32953892	1.62642668
9	0.69	-0.15	-60.8189345	-1.14017904	-0.36114262
10	0.74	-0.08	-33.4784871	-0.13518757	-0.0456263
11	0.63	-0.08	-30.1322485	-0.27000392	-0.09409191
12	0.41	-0.11	-24.8419359	-0.67126986	-0.23829684
13	0.66	0.02	-16.285714	0.08337423	0.03047471
14	0.27	0.06	-17.2991516	0.76529354	0.2811672
15	0.21	0.12	-43.9940696	3.2632119	1.03786889

Table 3.14: V Statistics from Engineering Workshop Data

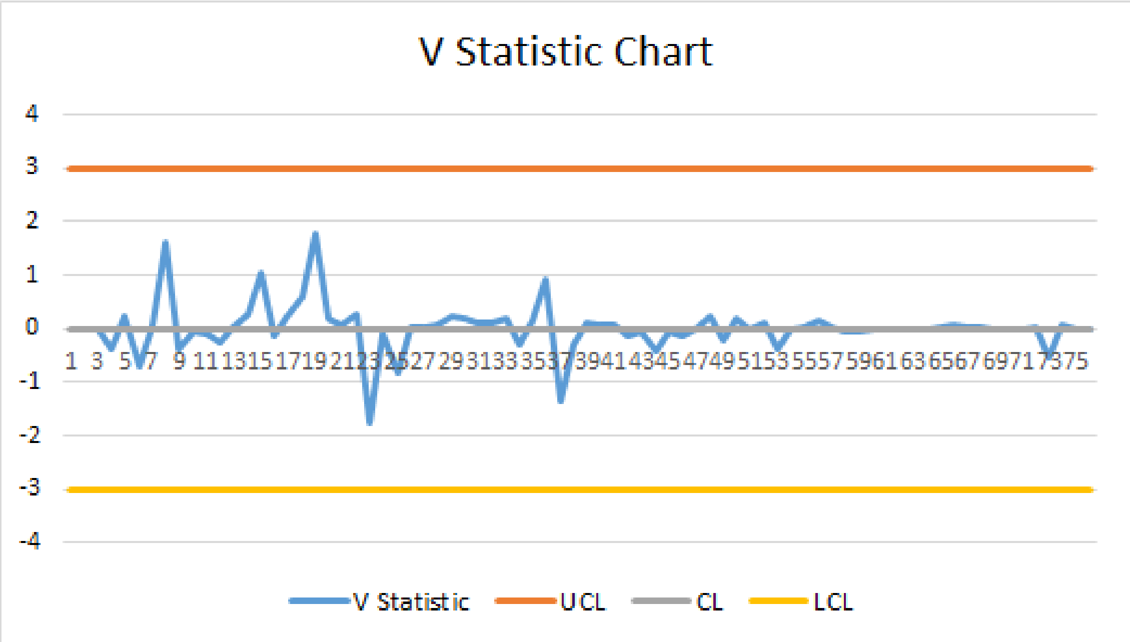


Figure 3.20: V Statistic Chart for Engineering Workshop Data

The V Statistic Control Chart shows an interesting trend, as many authors said. "warm-up period may be required so that a stable process can be established". Although, the chart shows a process in control, is easily to observe a data dispersion in the first 30 observations, from there, the data begins to be plotted very close to the central line, this seems to be the warm-up period. Although the performance of this control chart shows very favorable behavior, it is necessary to analyze the process more closely.

3.2.7 Summary

In this chapter, the application of SPC methods for low volume manufacturing have been developed. In the first case, SPC methods such as CUSUM, EWMA, and Q charts were presented and analyzed. These techniques focus on advanced control charts based on historical data. In the second case study, the implementation of SPC was more complex as consequence of the process. which was a low volume manufacturing, mixed batches, and also a multivariate process, producing different parts on the same machine. For this case, the approach was to analyze the process from its dispersion instead of analyzing it from their target values. In this way we standardize the collected data converting group of samples into individual measurements. The methods implemented were Individual X chart, Moving Range, Q chart, and V Statistic. Furthermore, in the following chapter comparison and discussion of results are going to be presented.

Chapter 4

Results and Discussion

In this chapter, research limitations, and results analysis and comparison are presented. Firstly, the limitations of this research are discussed. Secondly, graphic illustrations and representation the cases based on historical data, mixed batches, and multivariate process are illustrated separately. Thirdly, differences and similarities are shown for the different cases and methods. Finally, an explanation of the most appropriate method regarding on different scenarios for reliable application and accurate results are given.

4.1 Research Limitations

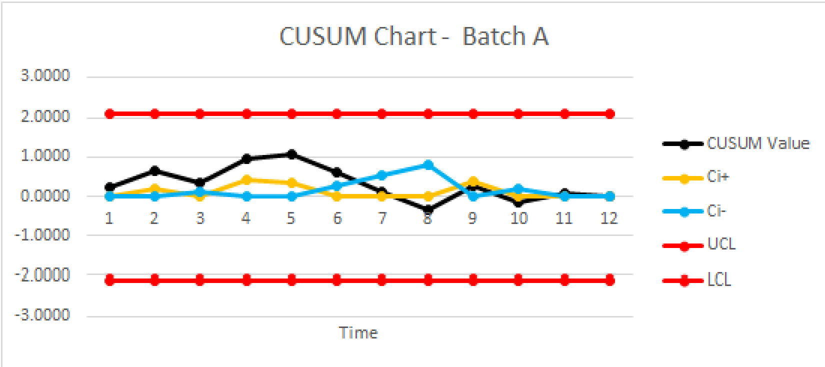
The findings of this thesis are subjected to a major limitation. The lack of data from the processes for estimation of the control parameters is the main limitation to use SPC analysis for low volume industries. In this thesis this has represented a constraint to apply SPC methods for short production runs. Despite the insufficient data, it was possible to implement SPC methods by processing values into operational data for the methods.

4.2 Advanced Control Charts for Low Volume Manufacturing Based on Historical Data

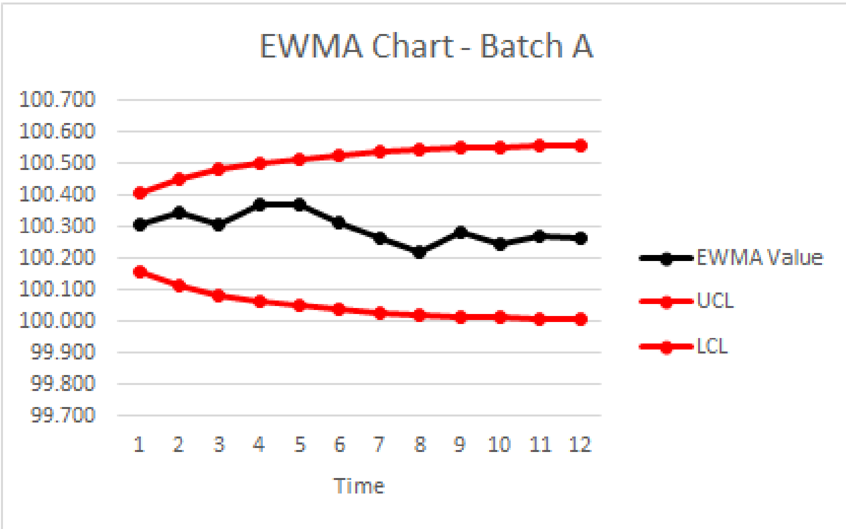
The first case is shown in chapter 3, section 3.1 ”Control Charts for Low Volume Manufacturing Based on Historical Data”. The objective in this scenario was to define the most appropriate method to analyze the process. A single product would be fabricated in this process. Moreover, only one variable is considered as a quality characteristic. The only data available were only four batches collected from a short run production before the continuous process start running.

Due to the characteristics of this case, applying traditional SPC techniques are not viable. Using the traditional SPC methods with this amount of data would result in unwieldy control limit. At the same time, in other cases. the probability of a false alarm could increase considerably. Additionally, the method would be incapable to detect shifts in the process. Therefore, alternative methods for short runs production must be implemented.

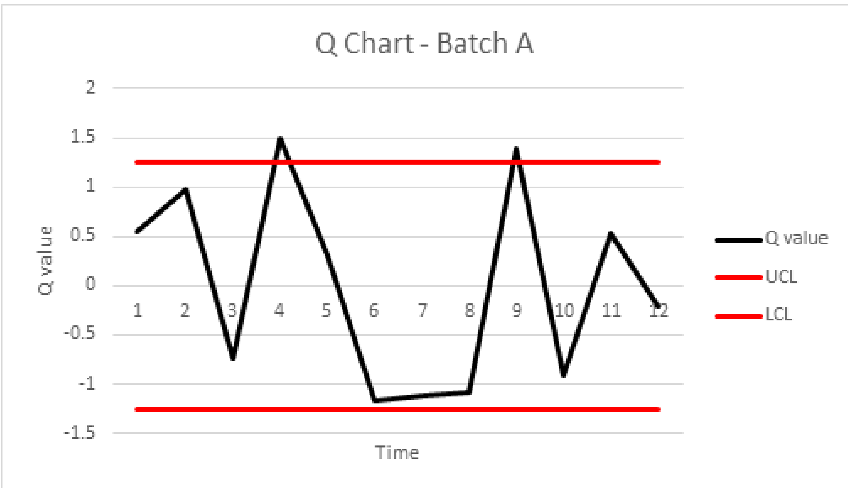
In figure 4.1 the results of the three different alternative methods used in this situation are shown. Figure 4.1a display the in-batch CUSUM chart for the continuous data set A. It can be seen that the CUSUM value sits comfortably between the control limits and stabilizes between the upper and lower CUSUM limits as time increases. This could be attributed to the machine reaching a steady state over time. Similar results can be seen from the in-batch data for B, C and D, which are shown in chapter 3. Additionally, figure 4.1b shows the results of the in-batch EWMA control chart for the continuous data set A. The variable upper and lower control limits are set in a similar way to the Western Electric limits and are dependent on the data values. The control limits are tight within these charts and the EWMA value shows little variation. However, it is difficult to draw any other conclusions other than the process being in control for these charts. Differently, figure 4.1c shows the results of the in-batch Q control chart for the continuous data set A. The method amplifies the variation of the process until exceeding the control limits. Also, the risk false warnings being triggered while missing slow changes in the mean over time.



(a) CUSUM Chart for Batch A



(b) EWMA Chart for Batch A



(c) Q Chart for Batch A

Figure 4.1: Advanced Control Charts for Short Runs Based on Historical Data, where Time in each graph refers to sampling time

Comparing the result charts of the three methods, a suitable method for this manufacturing scenario can be determined. Incorporating current and previous data values from the process, the CUSUM method increases sensitivity detecting small shift in the process. An appreciation of the previously stated is presented in the CUSUM results chart 4.1a. In contrast, the EWMA control chart shows lower sensitivity than CUSUM. The probability of not detecting small shifts increase over time, due to the exponential weighted control limits, which are also dependent on the data values. Afterwards, Q charts proved to be the method with the greatest dispersion in their control chart. An example is shown in figure 4.1c where the process is out of control.

CUSUM, EWMA and Q charts all provide the means to analyze low volume processes. Although the CUSUM and EWMA methods are similar, EWMA requires more data values in order for the control lines to stabilize. The CUSUM charts produced contain the most information and are the most comprehensive out of the three methods.

To sum up, it can be seen that even with a few data points, the CUSUM chart can provide a steady and reliable indication of control with minimal noise interference. In contrast, the EWMA and Q charts provide less useful information. It is important to note that the EWMA chart limits have not yet approached their steady state value by the end of the data. With a small set of data, any deviation from the target can greatly affect the control limits.

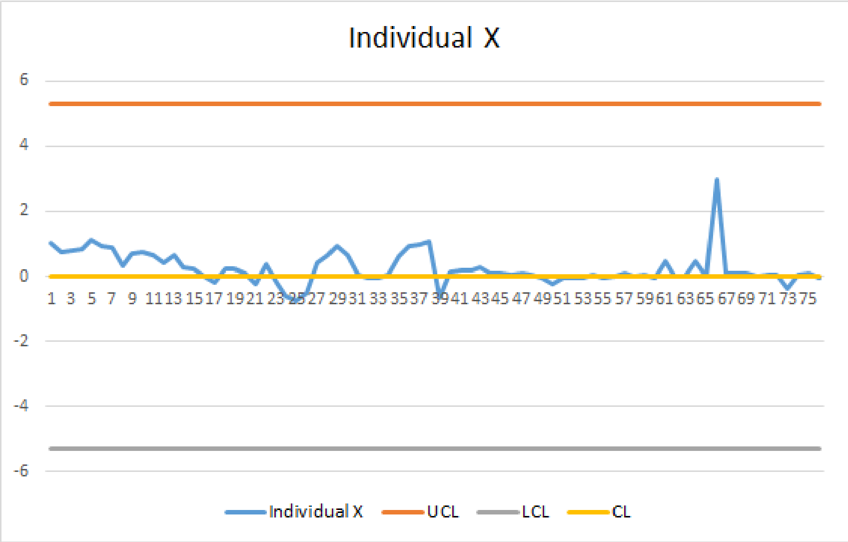
4.3 Control Charts for Short Runs Based on Mixed Batches and Multivariate Processes

The second application case refers to methods for two different scenarios. Control Charts for Short Runs Based on Mixed Batched and Multivariate Processes. The first scenario is shown in chapter 3, section 3.2.1. The objective in this case was to implement alternative SPC methods for short runs and mixed batches. Similar characteristic of different parts were fabricated in this production process. In order to obtain more reliable data, the samples were collected from the Engineering Workshop at Durham University. Due to the complexity of the case, alternative methods for short runs and mixed batches were developed.

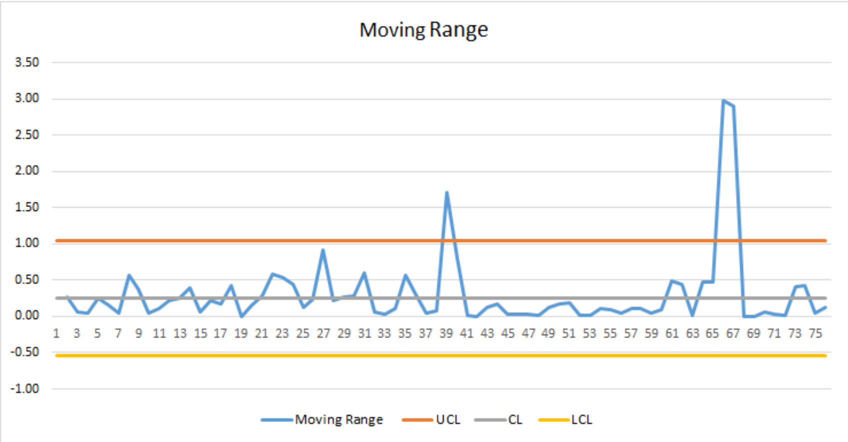
In figure 4.2 the results of the three different alternative methods used to control similar characteristic of different parts on a single chart are shown. The control charts described are focused in the process rather than the mean value. First, figure 4.2a shows the control chart for Individual X values. For this method, the sub grouped data collected were transformed to individual measurement errors, plotting deviations from the target value. Second, figure 4.2b displays the control chart for moving range values. This chart plots the absolute value of the difference between each two consecutive individual measurements. Finally, Q chart is shown in figure 4.2c. Q statistic values are plotted in this control chart, with standard normal control limits. This plotted values were calculated using the equations for the case when the parameters of the process are unknown.

In order to compare the results, the control charts are analyzed. Figure 4.2a shows the Individual X chart used when the sampling size is one. The Individual X values of the appropriate characteristic on each part were calculated and plotted in the chart in their production sequence. The results regarding to the variation pattern of the process indicates a sensitivity detecting shifts, as can be seen in point 66. To identify whether the reason of the shift is an assignable cause or a false alarm, it is necessary to execute a detail analysis of the process. Also, the control limits seem to have a significant slack according to the Individual X values. In contrast, moving range control chart displayed in figure 4.2b shows a process out of control. The observations 39, 66 and 67 exceed the control limits. Although, the individual X and the moving range have a similar behaviour, both in the observation points. The individual X seems to be in control, differently to the moving range. This discrepancy is due to the special constant value for each method. The constant being 2.66 for the individual X and 1.128 for the moving range, results in wider and thinner control limits. Figure 4.2c illustrates a non conventional response. At the beginning of the movement the Q statistic points reaches a lower value under the lower control limit. After, start an upward trend until process stabilizes. This is known as a "warm-up" stage. The rest of the data points are similar to the other two methods. A shift is recognized in point as well as in the other methods. Regarding the control limits, contrary to the other techniques, this chart has standardized control limits of ± 3 standard deviations.

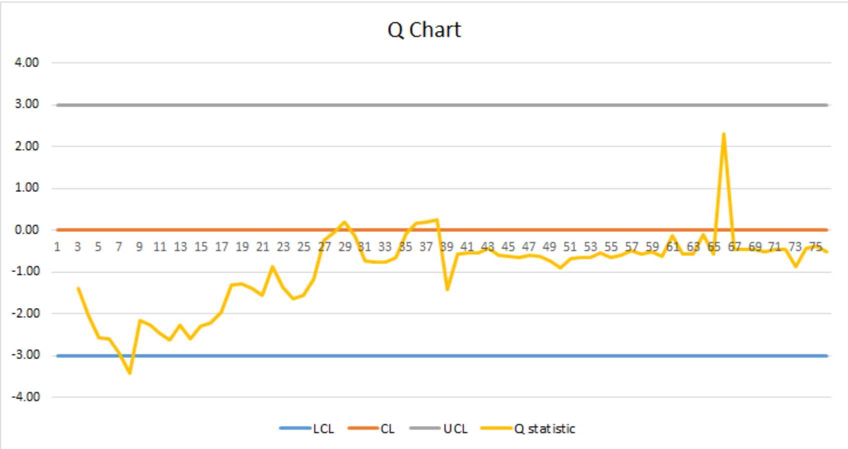
As a conclusion, the implemented methodologies above are appropriate in these type of scenarios. These methods are suitable for conditions in which the sample size is one. In addition, in cases where the short runs production considers mixed batches with different target values.



(a) Individual X Chart for Engineering Workshop Data



(b) Moving Range Chart for Engineering Workshop Data



(c) Q Chart for Engineering Workshop Data

Figure 4.2: Control Charts for Short Runs Based on Mixed Batches

The second scenario is attributed to multivariate processes. The main objective in this case was to analyze and monitor different variables of a single part in the same control chart. As the name of mixed batches methods states, they consider mixed data regardless the batch it comes from. Similarly, EWMA, CUSUM and Q Charts are known as applicable methods for short runs. However, these are only used for a single variable analysis. For this reason, V statistic control chart have been implemented for multivariate processes. In order to implement the method, data were collected from the Engineering Workshop at Durham University. Data collected was processed as presented in section 3.

The resulting graph is shown in figure 4.3. The data plotted in this chart represents the standardized values of V statistic. The figure suggests that the process shows a dispersion in the first observation. Continuing after the dispersion face the process stabilizes within the control limits. The control parameters are established by the standardized three standard deviation control limits.

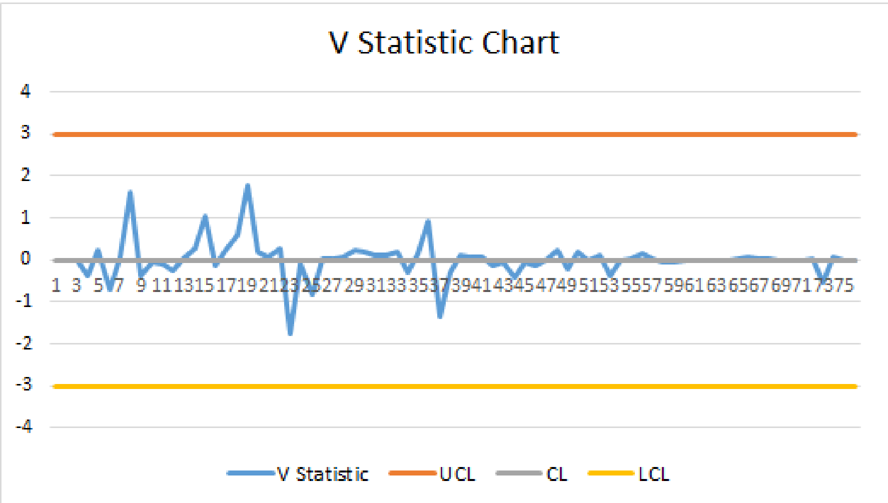


Figure 4.3: V Statistic Chart for Engineering Workshop Data

In summary, the advantages of the V statistic methods allow us to monitor processes with singular characteristics. For example, multiple variables for a process can be charted on the same chart because the plotted values are calculated on the standardized scale V statistic. In addition, the proposed chart can be used for process monitoring after the first few data are collected, because process parameters can be also estimated with this amount of data.

Chapter 5

Conclusion and Future Research

In this thesis different approaches of SPC methods for low volume manufacturing have been studied and implemented. The purpose of this research was testing the reliability, effectiveness, and results of advanced SPC methods in specific cases. In chapter 2, this thesis provides a reviewed research literature related to SPC methods for short runs production. In chapter 3, a few alternative methods have been applied. Also, the parameters and the plotted values were computed and their control charts were presented. In chapter 4, results are shown, explained, and discussed. Finally, in this chapter conclusions and future work are given.

The work carried out in this thesis was presented in chapter 3. Three study cases were selected to apply SPC methods. The first case was for short runs production based on historical data. EWMA, CUSUM, and Q charts methods were used to monitor processes with this type of data available. In the second case, data from short runs production and mixed batches were analyzed. Individual X, Moving Range, and Q charts techniques were implemented for this case. Finally, the last study case was multivariate processes, where different characteristics of a single parts were analyzed and plotted in the same control chart. V statistic method was used to monitor this special case.

The work in this research focused on the ability to detect shifts in the processes. Several other authors had conducted similar investigations. Their work, however, was mainly aiming at studying the detecting ability on the shift of the mean rather than process standard deviation. In this thesis, data collected was processed to individual measurements from the process deviation rather than the mean values. Converting the data to individual values the SPC methods for low volume manufacturing are viable to use.

Although the most adequate method for each specific situation was determined in this research, uncertainty of many other scenarios remain. A combination of the cases presented in this thesis might be studied. An example of this, the multivariate merged with mixed batches could be an interesting area for customizable industries. Furthermore, the development of a software with the possibility to estimate process parameters and control charts for the cases studied in this thesis.

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Appendix A

No	API 100mg. concentration	No	API 100mg. concentration	No	API 100mg. concentration
1	247.59	22	247.47	43	249.55
2	248.09	23	247.20	44	249.50
3	247.57	24	247.50	45	249.24
4	247.86	25	247.82	46	248.98
5	247.44	26	248.03	47	248.43
6	247.20	27	248.35	48	247.59
7	247.29	28	249.22	49	248.65
8	248.78	29	250.15	50	249.16
9	246.27	30	248.40	51	248.87
10	246.76	31	248.99	52	247.59
11	246.92	32	247.99	53	248.55
12	246.75	33	249.31	54	248.72
13	247.88	34	248.88	55	249.41
14	247.28	35	248.82	56	248.18
15	247.53	36	247.85	57	248.53
16	248.59	37	247.05	58	249.21
17	248.31	38	248.09	59	250.17
18	248.34	39	248.53	60	249.46
19	247.76	40	249.42	61	249.59
20	247.28	41	249.12	62	248.18

No	API 100mg. concentration	No	API 100mg. concentration	No	API 100mg. concentration
21	246.80	42	248.92	63	248.53

Table A.1: Data Collected from Batch Manufacturing Process API 100mg

No	API 50mg concentration	No	API 50mg concentration	No	API 50mg concentration
1	247.55	13	248.40	25	248.33
2	246.96	14	247.63	26	247.87
3	247.70	15	247.95	27	247.63
4	248.08	16	247.65	28	248.08
5	247.84	17	247.83	29	247.70
6	247.68	18	246.35	30	246.40
7	248.71	19	247.91	31	247.18
8	247.64	20	248.67	32	246.87
9	246.19	21	248.49	33	248.21
10	247.12	22	248.32	34	247.48
11	247.22	23	248.55	35	248.03
12	248.34	24	247.93	36	-

Table A.2: Data Collected from Batch Manufacturing Process API 50mg

Batch A			Batch B		
No.	Sample	API Concentration	No.	Sample	API Concentration
1	1	100.09	1	1	100.75
1	2	101.36	1	2	99.39
1	3	100.08	1	3	99.47
2	1	100.95	2	1	99.58
2	2	100.88	2	2	99.86
2	3	100.25	2	3	100.09
3	1	100.04	3	1	100.42
3	2	100.15	3	2	100.45
3	3	99.72	3	3	100.47
4	1	101.25	4	1	98.12
4	2	101.09	4	2	98.21
4	3	100.39	4	3	99.07
5	1	100.70	5	1	99.64
5	2	100.84	5	2	100.10
5	3	99.71	5	3	100.67
6	1	99.59	6	1	99.73
6	2	100.15	6	2	101.08
6	3	99.63	6	3	99.89
7	1	99.79	7	1	100.20
7	2	100.05	7	2	99.75
7	3	99.60	7	3	100.32
8	1	99.48	8	1	99.53
8	2	99.85	8	2	99.72
8	3	100.16	8	3	99.15
9	1	99.78	9	1	99.34
9	2	100.72	9	2	99.99
9	3	102.09	9	3	99.42
10	1	99.77	10	1	100.21

Batch A			Batch B		
No.	Sample	API Concentration	No.	Sample	API Concentration
10	2	99.99	10	2	100.24
10	3	99.92	10	3	99.95
11	1	100.81	11	1	100.00
11	2	100.49	11	2	100.77
11	3	100.21	11	3	100.54
12	1	100.08			
12	2	100.03			
12	3	100.48			

Table A.3: Data Collected from Continuous Process Batch A and B

Batch C			Batch D		
No.	Sample	API Concentration	No.	Sample	API Concentration
1	1	99.85	1	1	99.12
1	2	98.07	1	2	101.37
1	3	99.60	1	3	100.50
2	1	99.00	2	1	98.72
2	2	98.63	2	2	99.03
2	3	99.84	2	3	99.75
3	1	99.01	3	1	98.01
3	2	99.37	3	2	100.25
3	3	99.14	3	3	100.10
4	1	98.09	4	1	100.51
4	2	98.26	4	2	98.82
4	3	99.01	4	3	98.49
5	1	97.58	5	1	100.29
5	2	97.93	5	2	98.16
5	3	100.38	5	3	99.42
6	1	99.33	6	1	100.98

Batch C			Batch D		
No.	Sample	API Concentration	No.	Sample	API Concentration
6	2	97.94	6	2	100.12
6	3	98.52	6	3	101.01
7	1	98.39	7	1	99.84
7	2	98.62	7	2	100.24
7	3	100.15	7	3	97.75
8	1	98.67	8	1	98.10
8	2	98.63	8	2	99.03
8	3	97.60	8	3	98.43
9	1	100.50	9	1	103.61
9	2	97.97	9	2	99.71
9	3	98.09	9	3	97.85
10	1	100.19	10	1	98.57
10	2	100.04	10	2	97.74
10	3	98.78	10	3	99.52
11	1	99.55	11	1	100.55
11	2	96.64	11	2	99.68
11	3	99.69	11	3	99.96
			12	1	99.34
			12	2	98.33
			12	3	97.27

Table A.4: Data Collected from Continuous Process Batch C and D

Batch A				Batch D			
n	Xi	μ	σ	n	Xi	μ	σ
1	100.5112	100.2831	0.42	1	100.3308	99.4494	0.78
2	100.6932	100.2831	0.42	2	99.1675	99.4494	0.78
3	99.9712	100.2831	0.42	3	99.4545	99.4494	0.78
4	100.9114	100.2831	0.42	4	99.2721	99.4494	0.78
5	100.4151	100.2831	0.42	5	99.2919	99.4494	0.78
6	99.7921	100.2831	0.42	6	100.7050	99.4494	0.78
7	99.8127	100.2831	0.42	7	99.2782	99.4494	0.78
8	99.8299	100.2831	0.42	8	98.5192	99.4494	0.78
9	100.8632	100.2831	0.42	9	100.3896	99.4494	0.78
10	99.8964	100.2831	0.42	10	98.6069	99.4494	0.78
11	100.5039	100.2831	0.42	11	100.0624	99.4494	0.78
12	100.1966	100.2831	0.42	12	98.3140	99.4494	0.78
Batch B				Batch C			
n	Xi	μ	σ	n	Xi	μ	σ
1	99.8725	99.8817	0.56	1	99.1698	98.8801	0.40
2	99.8439	99.8817	0.56	2	99.1564	98.8801	0.40
3	100.4456	99.8817	0.56	3	99.1730	98.8801	0.40
4	98.4674	99.8817	0.56	4	98.4550	98.8801	0.40
5	100.1342	99.8817	0.56	5	98.6304	98.8801	0.40
6	100.2321	99.8817	0.56	6	98.5949	98.8801	0.40
7	100.0881	99.8817	0.56	7	99.0513	98.8801	0.40
8	99.4640	99.8817	0.56	8	98.3005	98.8801	0.40
9	99.5829	99.8817	0.56	9	98.8527	98.8801	0.40
10	100.1317	99.8817	0.56	10	99.6712	98.8801	0.40
11	100.4361	99.8817	0.56	11	98.6259	98.8801	0.40

Table A.5: Values of Xi, μ, and σ are calculated from Continuous Process Batch A, B, C, and D.