



Journal of Turkish Operations Management

Application of statistical process optimization tools in inventory management of goods quality: Suppliers evaluation in healthcare facility

Mostafa EİSSA^{a*}, Engy RASHED^b

^aFaculty of Pharmacy, Cairo University, Cairo, Egypt

e-mail: mostafaessameissa@yahoo.com, ORCID No: <https://orcid.org/0000-0003-3562-5935>

^bNational Centre for Radiation Research and Technology, Cairo, Egypt

e-mail: engyrefaat@yahoo.com, ORCID No: <https://orcid.org/0000-0002-6593-378X>

*Corresponding author

Article Info

Article History:

Received: 20.03.2020

Revised: 10.05.2020

Accepted: 30.06.2020

Keywords:

Statistical process control,
Inventory,
Healthcare,
Control charts,
CSV dataset

Abstract

Inventory management and control represent a crucial activity required in any successful organization for the modern industry generally and the healthcare field specifically. Rigorous monitoring of the goods inspection properties is important for the delivery of products with appropriate quality that meets customer needs. In the present study, random records have been selected that cover a year simulation period of monitoring for container deliveries to a warehouse that were used as primary packaging materials for topical healthcare products from three different manufacturers. Statistical Process Control (SPC) methodologies and analyses such as box plots, histograms, Pareto diagrams, process-behavior charts and Gaussian Mixture Model (GMM) were applied for processed and stratified data to evaluate a single product property. Integration between the material stock database and statistical processing platform was established through excel dataset and/or Comma-Separated Values (CSV) files where the results of the monitored inspection characteristic were reported for each freightage. The analysis showed that the most dominant supplier dispatched products with specifications that have become very close to the target value, despite initial unstable variations in the inspection characteristic. The less common manufacturer showed product quality values that are shifted slightly above the previous one with a lower rate of out-of-control alarms. The least contacted vendor demonstrated the highest precision (which might be partially accounted to a very few numbers of the received batches of the packaging product) with the lowest accurate values that were very close to the upper specification limit. The study was useful in manufacturers' quality assessment and follow-ups.

1. Introduction

Adequate management and control of inventory is a critical practice in any organization to ensure an appropriate supply of the essential goods in a timely manner without shortage or overstocking (Rachmania and Basri, 2013). Moreover, the status of goods delivery should be achieved by meeting the required specifications without unacceptable defects (National Research Council, 2000). In business terms, the on-time distribution of high-quality shipments would ensure customer satisfaction, which would be reflected in the company image and profitability in the competitive market world. Hence, special statistical methodologies are useful in such circumstances for the monitoring, control and investigation of the quality of the goods, in addition to the support for the identification of the possible roots of the departure from the target value of inspection characteristic for the product.

One of the widely used and applied modern methods started early in the twentieth-century and known as Statistical Process Control (SPC). SPC techniques have been used for decades in the modern industry in the monitoring, control and improvements in various processing steps (Eissa and Abid, 2018; Oliveira et al., 2019). Various tools adopted in SPC were aimed to ensure consistent, reproducible and stringent product quality with minimal defects or wastes (Montgomery, 2013; Carey et al., 2018), in addition to the opportunity of enhancement through learning from the processes investigations of the examined inspection characteristics. The application of SPC tools in inventory management and control would be a useful means for quality improvement and resources management for both intermediate and final product components materials.

The application SPC - including process behavior charts - has been demonstrated before in other studies. Some researchers applied it to reduce the bullwhip effect (Iyer and Prasad, 2007). Others have used it to monitor inventories accuracies (Huschka, 2009). Lightfoot and Kauffman (2003) have shown the applicability of the use of control charts to evaluate and control the performance of the inventory. Simulation and evaluation study for inventory management through SPC was also demonstrated by other investigators (Pfohl et al., 1999). The usefulness of SPC methodologies has been extended to enhance the supply chain dynamicity through inventory control policy that is centered on SPC to minimize bullwhipe effect and inventory instability (Costantino et al., 2015). Meanwhile, an SPC-based study that controls goods quality of the materials delivered to warehouses would be useful in risk mitigation of the non-conforming products and investigational analysis to identify the sources of deviations and possible excursions.

The present study aimed to investigate product quality from different suppliers through the adoption of SPC methodologies using commercial statistical software packages in the supply chain planning. The studied case would provide a detailed systematic mean of the analysis to revise, correct and improve product quality through monitoring of one of the inspection properties from different vendors. The current case model was sifted stepwise by the application of SPC analysis to control the product inspection property quality through statistical segregation and grouping which would identify the main contributors for the deviation from the target value with a possible risk of the excursion. The terms "delivery" and "shipping" will be applied herein synonymously because the current case applied for it and almost abolished the differences such as sending and reception dates were the same due to closeness of the geographical regions.

The work will focus on the chronologically arranged database of one year of the warehouse stock record from the inventory management platform system. The result of the inspection characteristic (herein thickness in μm) for each batch could be traced to a defined supplier (identified by a specific code) as a source for the income good. Preliminary evaluation using a control chart supported by a histogram would provide a useful mean for the screening of data patterns to identify unusual distribution and trends. The initial identification of the main supplier and the major product-per-vendor using the Pareto plot is useful for spotting the critical focus groups that impart their impact on the overall quality of the incoming goods. If data distribution from the preliminary study showed a pattern of mixed Bell-distribution then the Gaussian distribution resolution study was used to define the long-run pattern of the inspection property. Accordingly, two-dimensional analysis for the possible deviations could be adopted: Firstly, the isolated Gaussian distributions. Secondly, data stratification based on the manufacturer. The 2-D study could be initiated using descriptive statistics and a Box plot diagram. Individual study for each segregated dataset was then studied using process-behavior or trending charts supplemented with the Pareto plot to identify the major influential factor in each data cluster. The final outcome from this study would be spotting the major complying and stable product, in addition to the vendor goods quality. This would help in resources management to focus on high-risk goods and suppliers to set Corrective and Preventive Actions (CAPA) before any excursions or out-of-specification (OOSs) occur due to defective products from a non-competent manufacturer.

2. Material and Method

A random one-year dataset pattern was selected for inventory goods that simulate shipments deliveries to the warehouses in a healthcare facility (Bartholdi and Hackman, 2014; Bienert, 2018). Systems, products and applications in records handling were all integrated so that interconnected information pieces are all gathered in a single spreadsheet. In the present case, vendors, suppliers and manufacturers were used synonymously as the sources organizations of the products served for these functions simultaneously. In addition, the manufacturers of packaging products used the terms "batch" and "lot" synonymously.

2.1. Vendor And Product System

Three suppliers were available for supplying containers for semisolid skincare products and denoted by ewH, ube and upl. Seven products that would be packaged in these packaging materials (PM) were given codes FLHI, FTCC, FTOC, FTOO, TOFO, TZOC and ZTHI. For the purpose of traceability for PM to the vendor, the tracking codes could be assigned as Material/Supplier (M/S) designation codes, for example, material TZOC that would be filled in PM from the manufacturer ewH would be named TZOCewH. Each vendor should be able to deliver primary PMs with common, consistent and reproducible quality criteria that cover all types of topical healthcare products.

2.2. Quality Inspection Characteristic

An important quality aspect that had been inspected was PM thickness (in μm). The container should be strong enough to hold the product sufficiently protected against any leakage during exposure to different types of mechanical pressure or force (Center for Biologics Evaluation and Research, 2003). Nevertheless, it should be adequately flexible to the normal squeezing action applied to deliver the product during the use and application to the skin. The acceptance range was established between 130 to 170 μm . For all mentioned suppliers and products, the same quality inspection criterion of the container was applied. The monitoring period involved six months in duration.

2.3. Dataset Management System

Deliveries from different suppliers were registered and recorded using an electronic inventory management system with the supplier code, product code, date and time (Deelman et al., 2005; Cato and Mobley, 2002). The quality inspection results of the sampled materials arrived at the warehouse were also incorporated into the inventory management system database (Muller, 2019). The database was created and the record arranged chronologically with the inspection results recorded for each lot. Then, data processing using statistical process control (SPC) software to plot the control or process-behavior (trending) charts, Pareto diagram and histograms (Eissa, 2019a; Eissa, 2019b). On the same line, other programs generate descriptive statistical analysis reports and Gaussian Mixture Model (GMM) probability data based on suspect mixed distributions that could be expected from both trending chart and histogram visual pattern (Thompson, 2011; Moraru et al., 2019). The established pivotal connection for network platform between the warehouse and data-processing programs is through Comma-Separated Values (CSV) or Excel file data system through which data segregation and stratification were done, in addition to a built-in GMM creation program. This concept could be exemplified simply in Figure 1.

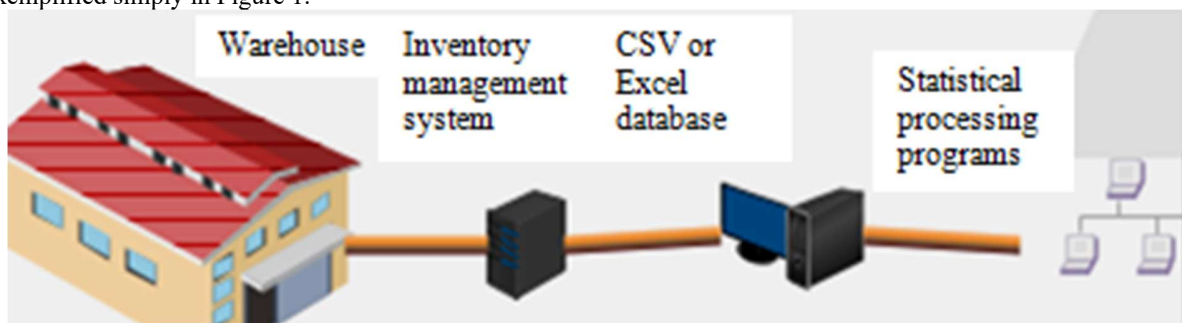


Figure 1. Simplified diagram showing major steps of quality inspection of delivered goods to a warehouse

2.4. Statistical Techniques Used In The Analysis Of The Database Through SPC Software

GMM was conducted using built-in XLSTAT v2014 and the column statistics was generated through GraphPad Prism version 6.01 for Windows. While, process-behavior charts, histogram, Pareto diagram, box and whisker diagram were created using Minitab version 17.1.0. Detailed referenced processing equations and calculations are available with each software manual.

2.4.1. GMM As A Tool For Segregation Of Random Data

In statistics, a mixture model is a probabilistic version for representing the presence of subpopulations inside an overall populace, without requiring that an observed information set must discover the sub-population to which a person

observation belongs. Formally, an aggregate version corresponds to the aggregate distribution that represents the chance distribution of observations inside the overall population (Celeux and Govaert, 1992; Reynolds and Rose, 1995; McLachlan and Peel, 2006). This analysis technique was used to spot a clustering pattern of the random data of the monitored inspection characteristic and assess the degree of the consistency of the thickness of the containers.

2.4.2. Histogram: An Initial Step In Data View

The histogram is one in every of the most regularly used display tools because it gives a completely quick concept of the distribution of a pattern of continuous or discrete data. Intervals definition: One of the challenges in creating histograms is defining the durations, as for a decided set of records, the shape of the histogram relies upon solely at the definition of the classes. Between the 2 extremes of the single class comprising all the information and giving a single bar and the histogram with one figure per a single class, there are as many feasible histograms as there are records partitions. To acquire a visually and operationally satisfying result, defining classes may require numerous attempts. The common traditional technique is composed of the use of classes defined via periods of the equal width, the lower certain of the first interval being decided by using the minimum value or a number slightly much less than the minimum figure (Chambers et al, 1983; Jacoby, 1997; Wilkinson, 1999). Through histogram shape, data pattern would reveal the possible presence of mixed distribution due to a mixed operations or interfering heterogeneous properties.

2.4.3. Box Plot (Boxplot Or Box-And-Whisker Diagram): Data Spreading Comparison, Visualization And Outlier Detection

Box-and-Whisker plot or boxplot is a way for graphically presenting a dataset of via their quartiles. Boxplots may also show lines projecting from the boxes (whiskers) indicating variability beyond the higher and lower quartiles, for this reason, the terms box-and-whisker plot and box-and-whisker diagram. Outliers can be plotted as individual points. Box plots are non-parametric: they display variant in samples of a statistical populace without making any assumptions of the underlying statistical distribution. The spacing among the unique elements of the box suggests the magnitude of dispersion (spread) and skewness in the records, and display outliers (Tomassone et al., 1993; Sokal and Rohlf, 1995). Visualized data in Box plot could be detailed numerically using column statistics in tables. Box plot finds its place in 2-D data analysis to visualize and compare the fluctuation of the inspection property value through both the manufacturers and GMM routes.

2.4.4. Pareto Diagram And The Identification Of The Major Contributor(S) In A Single Step Of The Analysis

A Pareto chart draws its call from an Italian economist, however J. M. Juran is credited with being the first to apply it to commercial problems. The causes that should be investigated (e. G., nonconforming items) are indexed and possibilities assigned to everyone so that the whole is 100 %. The percentages are then used to construct the diagram that is essentially a bar or pie chart. The Pareto analysis uses the ranking reasons to decide which of them ought to be pursued first (Juran, 1960; Pyzdek, 2009; Ryan, 2000). Accordingly, Pareto analysis would be useful to focus on the major products/vendors that could impact the monitored quality characteristic.

2.4.5. Control (Shewhart, Process-Behavior Or Trending) Chart: Quantitative Evaluation Of The Quality Characteristic In A Time-Order Manner

Attributes control charts are comparable in components to variables trending charts, besides that they plot statistics from count data as opposed to measurement data. For instance, products can be compared with a reference control values or limits and categorized as both being faulty or not. Products will also be categorized by counting the number of defects. As with variables Shewhart charts, a process statistic, including the number of defects, is plotted as vs. to a specimen quantity or time. SPC software draws a middle line at the common of the statistic being plotted in the interim charted. Computer programs can also draw two different lines - the higher and lower threshold limits - 3 standard deviations above and underneath the middle line, as default. Since the limits, tolerance and measurements provided herein in this study are integers only, the attribute charts were applied with Laney modification to adjust for data dispersion. The computation for the Laney U' chart includes Sigma (σ) Z, which is correction for overdispersion or

underdispersion. A σZ figure of one is indicative that no alteration is required and that the Laney U' chart is exactly the same as a conventional U chart (Jones and Govindaraju, 2001; Montgomery, 2013; Laney, 2002; Ryan, 2013).

3. Results

The implementation of SPC application was extended beyond the control and the monitoring of the inspection characteristic quality to a systematic investigation for improving incoming goods property (thickness) and minimization of the deviation risk from the target value to avoid future excursions.

3.1. Preliminary Assessment Of The Overall Trend For The Inspection Property

All results of the monitored property had met the acceptance criterion range of $150 \pm 20 \mu\text{m}$ for the primary packaging material thickness. Overall chronological charting of the inspection characteristic for all delivered shipments yielded trending behavior as could be seen in Figure 2. A green line indicates the mean value, while the upper control limit (UCL) and lower control limit (LCL) were shown as red lines above and below the average trend line. Two distinct patterns were observed: initial fluctuating with out-of-control points (lots) which ceased gradually towards a more stable variation despite few intermittent aberrant values. Number "1" alarm is interpreted as: One point more than 3.00 standard deviations from center line. Test for out-of-control values has failed at points: 2 (TZOCupl), 8 (FLHIewH), 14 (FTCCewH), 22 (ZTHIupl), 23, 24, 25 and 107 (FLHIewH), 40, 41 and 44 (FLHIube), 54 (TZOCube), 81 (ZTHIube). Histogram of total shipments - with interval definition of 12 - suggested mixed distribution as it would be observed from Figure 2. Thus, overlapping datasets segregation might be required to be analyzed.

3.2. Investigation Of The Major Contributors Using Pareto Analysis

An investigational study using Pareto analysis showed that data could be stratified through more than one perspective as could be seen in Figure 3. Most shipments (>70%) came from one supplier viz ube and FLHI accounted for approximately 60% of total products from the three vendors. The least deliveries came from ewH (only six). The descending order of the deliveries rates for the remaining products FTCC, TOFO, ZTHI, FTOO and TZOC were about 14, 9, 7, 6, 5 and 2%, respectively. Manufacturer "ube" was the major source of FLHI, FTCC, TOFO, ZTHI and FTCC types of containers, respectively.

3.3. Dataset Stratification Approaches

Elucidation of the source of the abnormal variation due to assignable causes was conducted through two perspectives: GMM and vendor approach.

3.3.1. GMM analysis using built-in XLSTAT v2014

The first logical approach was to separate database based on data tendency for clustering after reporting a pattern in Figure 2. According to the Bayesian Information Criterion (BIC), the best mixture model is the Data dimension with two component(s). The Expectation–Maximization (EM) algorithm converged in 31 iterations. The optimal number of classes occurs at the min choice. The algorithm should be run with a minimal number of classes fewer than two. Since the calculated Normalized Entropy Criterion (NEC) is lower than one, there is a clustering structure in the data. Appropriate GMM pattern was found to be a mixture of two interfering bell-shaped distributions for the inspection characteristic as could be visualized in Figure 4 with proportions of class I/II were 0.3709/0.6291. A sharp narrow peak (denoted by 2 or II) that is close to the target value (a desirable outcome) but slightly shifted to a slightly higher value and shallow highly dispersed bell-shaped distribution with strongly shifted mean upward (undesirable pattern). Quantile-Quantile (Q-Q) and Cumulative Distribution Function (CDF) plots provided a visual interpretation of the degree of closeness of the practical distribution with the theoretical assumed one. Based on Table 1, the thickness window range for distribution II resided between 150 and 151 μm , in contrast to the first were the quarterly separated ranges magnitudes were 10, 3.5, 2.5 and 7 μm . Hence, the standard deviations and errors for the first distribution was about ten times that of the second one. It should be noted that the mean of wider distribution is shifted above the target value. On the other hand the narrower distribution was almost centered on the required optimum value. This would lead to an in-between values for that for the overall analysis. Box plot in Figure 5 demonstrates the pattern of data spreading visually for both assumed distribution in comparison with the overall dataset showing the compactness of the second distribution, in contrast to the first one with notable outlier values in the lower side. Thus, the net dispersion is a

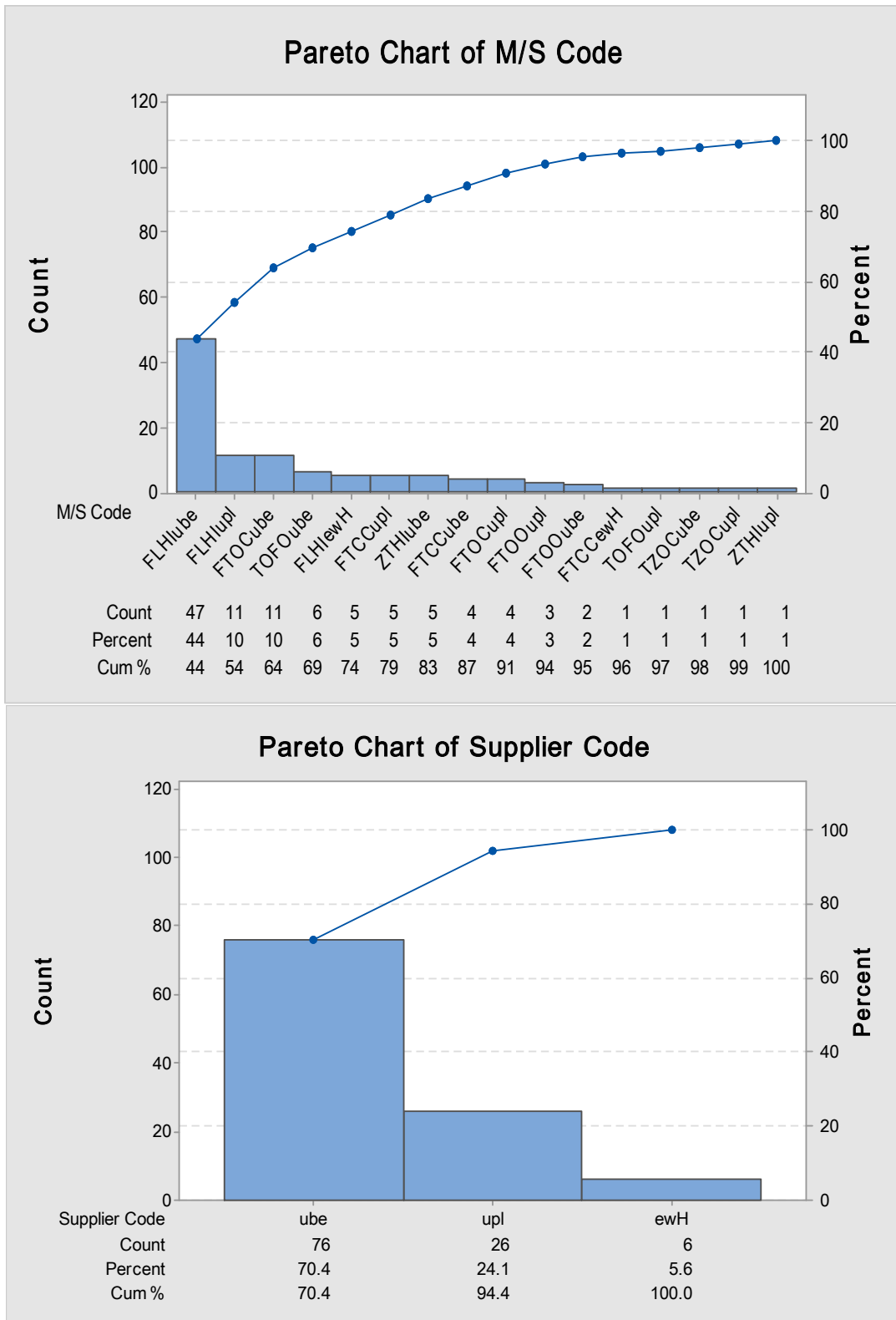


Figure 3. Two-dimensional Pareto diagram of supplier and material/supplier frequencies

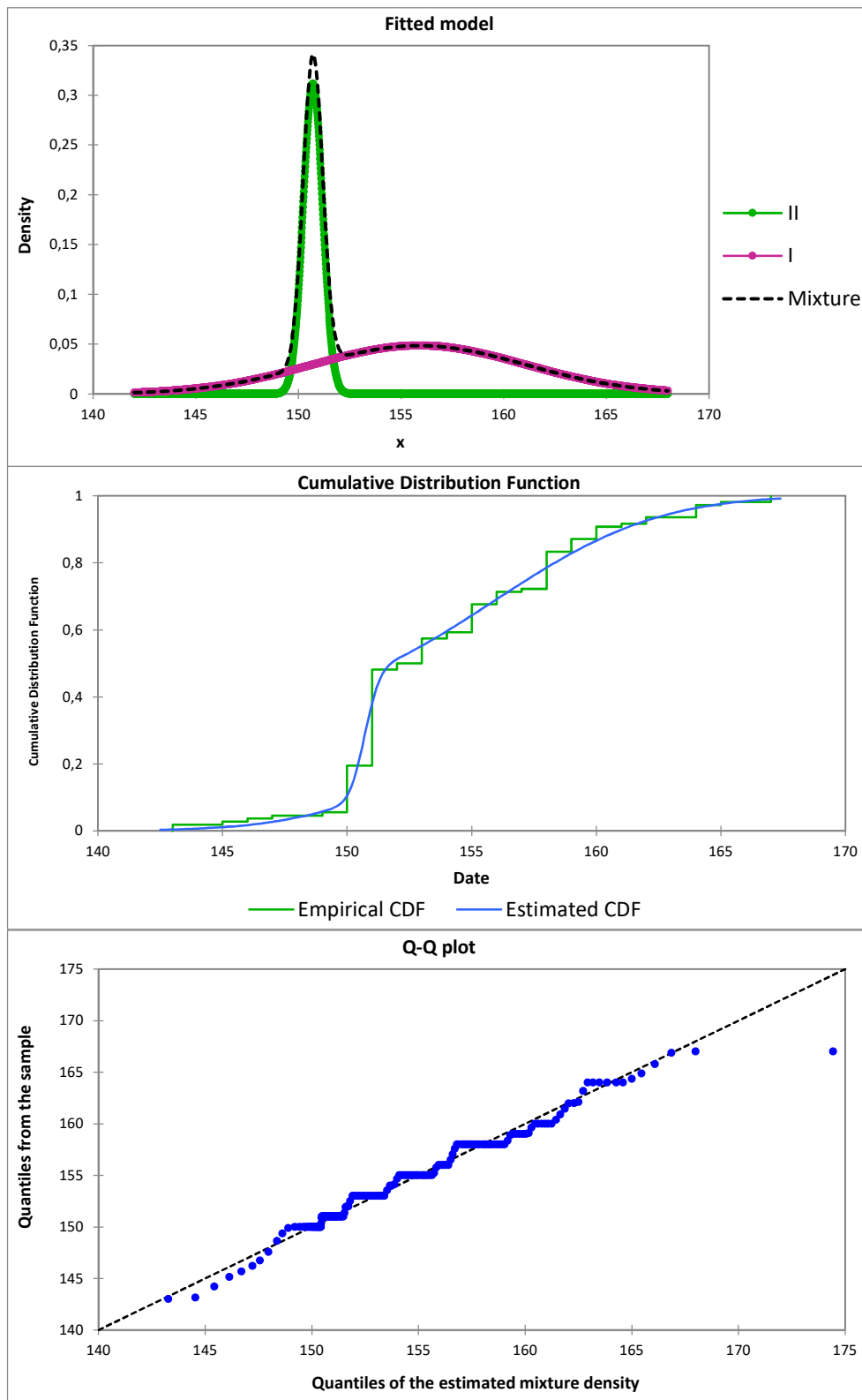


Figure 4. Gaussian Mixture Model (GMM) of packaging material average thickness distribution per incoming batch

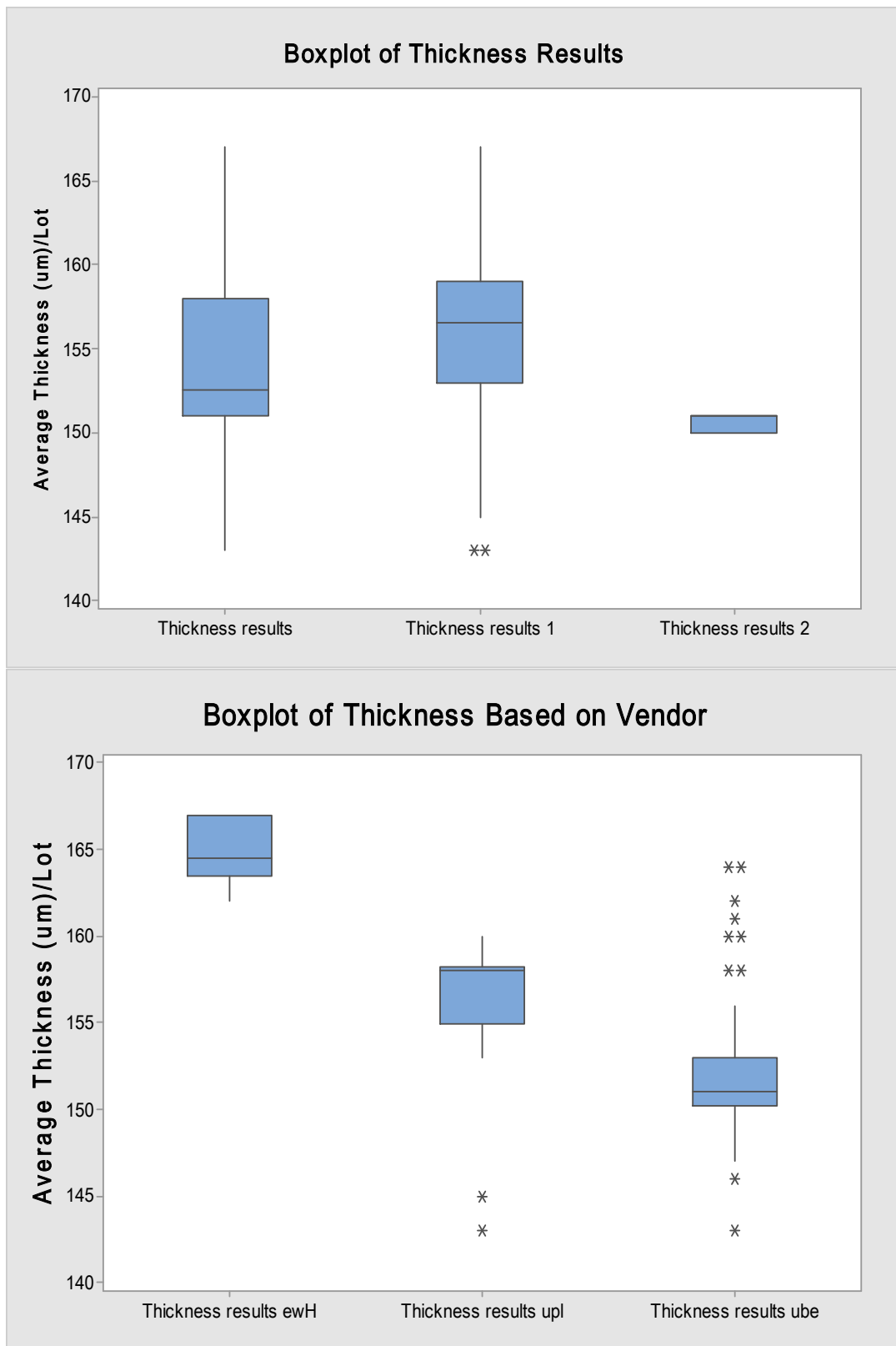


Figure 5. Box plot diagram for GMM-separated and manufacturer-stratified data (asterisks "*" outlier points)

Table 1. Descriptive statistics for overall and GMM-segregated record

Column Statistics	Thickness Results 2	Thickness Results 1	Overall Thickness Results
Number of values	46	62	108
Minimum	150.0	143.0	143.0
25% Percentile	150.0	153.0	151.0
Median	151.0	156.5	152.5
75% Percentile	151.0	159.0	158.0
Maximum	151.0	167.0	167.0
Mean	150.7	156.4	154.0
Std. Deviation	0.4740	5.161	4.835
Std. Error of Mean	0.06988	0.6555	0.4653
Lower 99% CI of mean	150.5	154.7	152.7
Upper 99% CI of mean	150.9	158.1	155.2
Normality test			
Passed normality test ($\alpha=0.01$)	No	Yes	Yes
P value summary	****	ns	*
ROUT (Q = 10.00%)			
Outliers	0	6	0

3.3.2. Data segregation based on the source manufacturer

The second logical approach in data segregation should be based on the supplying source manufacturer. The numerical analysis showing the trend of each supplier was done as column statistics in Table 2. While no outlier values could be detected from the few (six) batches from ewH manufacturer, aberrant records were detected in both upl (26 batches) and ube (76 batches) at rates 8% and 16% approximately, respectively. The range of the inspection characteristic variation for ewH, upl and ube was 5 μm , 17 μm and 21 μm , respectively. The ascending deviation from the goal value of 150 μm expressed as a mean \pm Standard Error of the Mean (SEM) was approximately 152 \pm 0.42 μm (ube), 156 \pm 0.80 μm (upl) and 165 \pm 0.79 μm . The Confidence Interval (CI) window at 95% - as calculated using statistical software - of both (mean and median) for ube, upl and ewH was (1.6/0.0), (3.3/2.0) and (4.1/5.0), respectively. These results were reinforced by the visual observation of the behavior of each vendor in the Box-and-Whisker diagram of Figure 5 showing the descending pattern (from left to right in graph) toward the target value accompanied by increasing number of the outlier values. The inspection characteristic of the least frequent ewH manufacturer was homogenous but the results were the farthest from the target value of 150 μm . In contrast, ube deliveries were the closest to the specification mean value, yet it had suffered from many aberrant records. Meanwhile, upl results were in between both suppliers.

3.4. Process-Behavior Charts And Pareto Diagrams For Clustered Data

Combination of chronologically arranged control charts and Pareto diagrams were used to investigate each one of the segregated data based on the above-mentioned perspective views.

3.4.1. GMM-based process behavior charts and Pareto plot

PM containers for FLHI products were almost equally distributed between the two phases of distribution - viz. 1 and 2 patterns - with contribution factor approaching 0.6 as could be evident in Figures 6 and 7. Figure 6 individual batches that exceeded the control limits at chronological points 2 (TZOCupl), 22 (ZTHIupl) and 58 (ZTHIube). This is in contrast of Figure 7 where no excursion of out-of-control lots was observed with steady behavior and narrow results

range. However, distribution II - which showed relatively stable variations in the inspection characteristic - stemmed only from one supplier viz ube. While the mostly initial unstable section involved the three vendors showing a wider limit window and included out-of-control points (marked by red dots) - that exceeded 3σ (Sigma) - from ZTHIupl/ube and TZOCupl. Other less common products contributions in distributions [I and II] included FTCC [13% (upl and ewH), 9% (ube)], FTOC [12% (upl and ube), 20% (ube)] and TOFO [2% (upl), 13% (ube)]. The PMs of the remaining products (~13%) were found only in distribution I.

3.4.2. Supplier-based process-behavior charts and Pareto plot

Segregation by the suppliers is shown in Figures 8 and 9. Trending charts demonstrates the tendency of shipments coming from ewH to shift to higher values above the target value with a possible risk to exceed the higher acceptance threshold. This minor manufacturer delivered five sixth of deliveries as FLHI. The next manufacturer with higher rates of supply was upl with a closer trend to the target specification value. However, two batches for TZOC (point 2) and ZTHI (point 20) were abnormally low results which could be observed below the target and exceed LCL value despite being within the specification limit. More than 60% of the deliveries from this vendor were PMs for FLHI and FTCC. The latest supplier with the most frequent shipments and the closest trend toward the target value was ube. Excursion values on the lower side of the control chart were found to be linked with the same products as was observed previously. However, the predominant product i.e. FLHI - with more than 60% contribution from the overall materials delivered from this manufacturer - demonstrated intermittent excursions in the initial section of the process-behavior chart at the direction above the UCL with alarming points "1" that exceeded 3 standard deviation at chronologically arranged lots 6, 7, 9, 10, 13 and 14 (FLHIupe), 23 (TZOCube) and 50 (ZTHIupe). Number of batches of ewH vendor are few to confirm it consistency and hence stability without out-of-control points.

Table 2. Descriptive statistics for supplier-segregated record

Column Statistics	Thickness Results ewH	Thickness Results ube	Thickness Results upl
Number of values	6	76	26
Minimum	162.0	143.0	143.0
25% Percentile	163.5	150.3	155.0
Median	164.5	151.0	158.0
75% Percentile	167.0	153.0	158.3
Maximum	167.0	164.0	160.0
Mean	164.8	152.3	156.3
Std. Deviation	1.941	3.659	4.087
Std. Error of Mean	0.7923	0.4197	0.8015
Lower 99% CI of mean	161.6	151.2	154.1
Upper 99% CI of mean	168.0	153.4	158.5
Normality test			
Passed normality test ($\alpha=0.01$)	Yes	No	No
P value summary	ns	****	****
ROUT (Q = 10.00%)			
Outliers	0	12	2

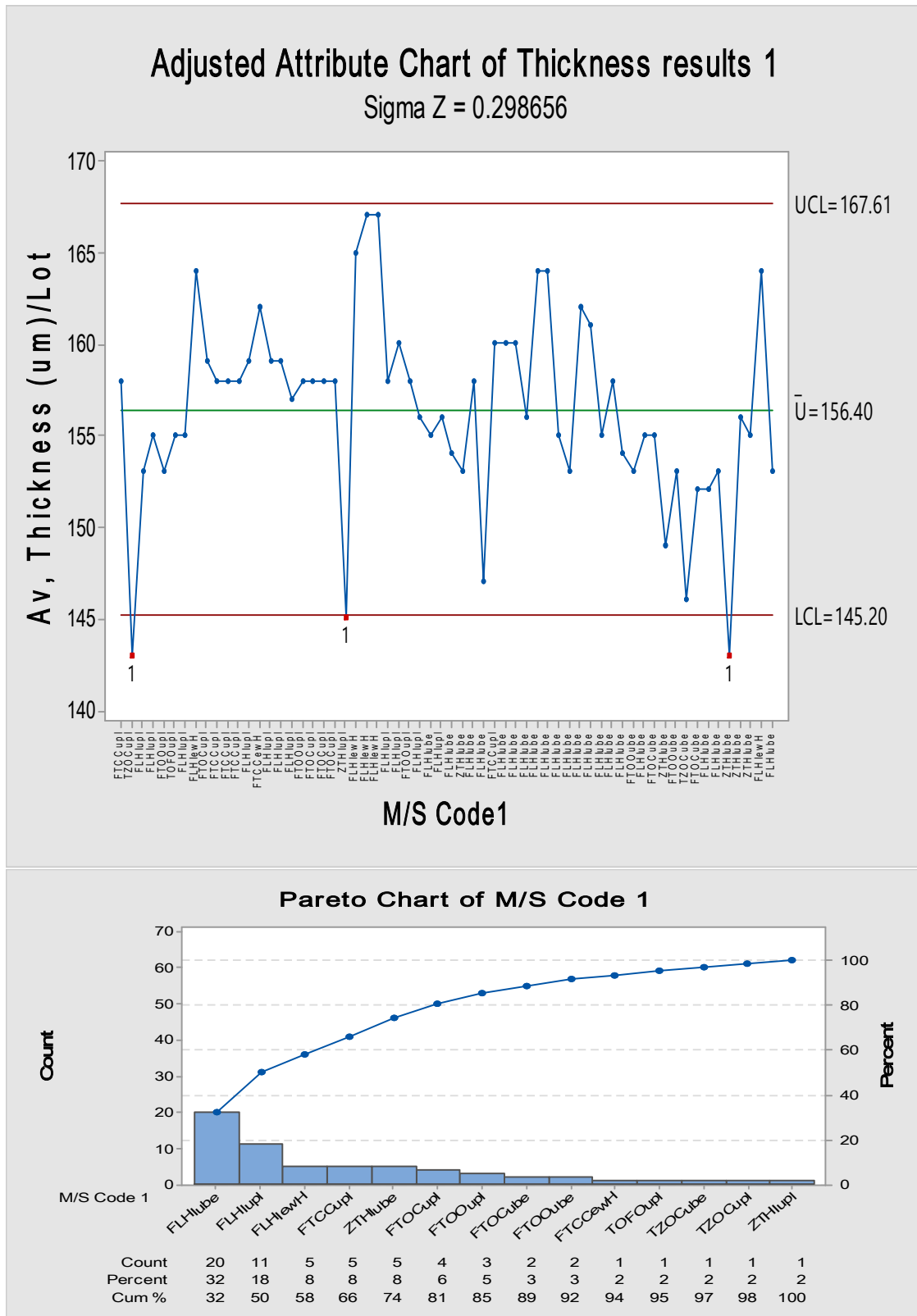


Figure 6. Process-behavior chart and Pareto diagram for distribution I based on GMM stratification

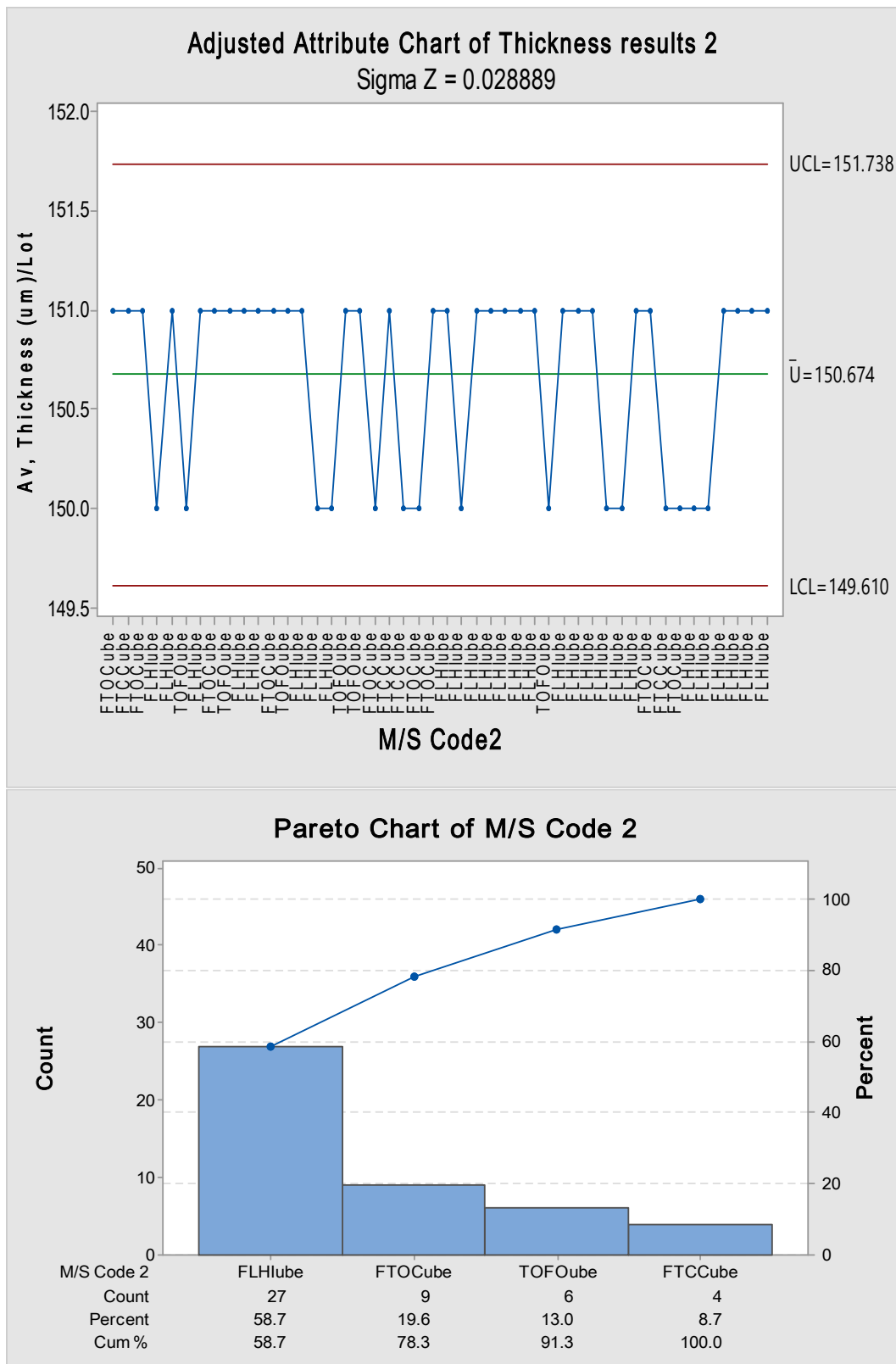


Figure 7. Process-behavior chart and Pareto diagram for distribution II based on GMM stratification

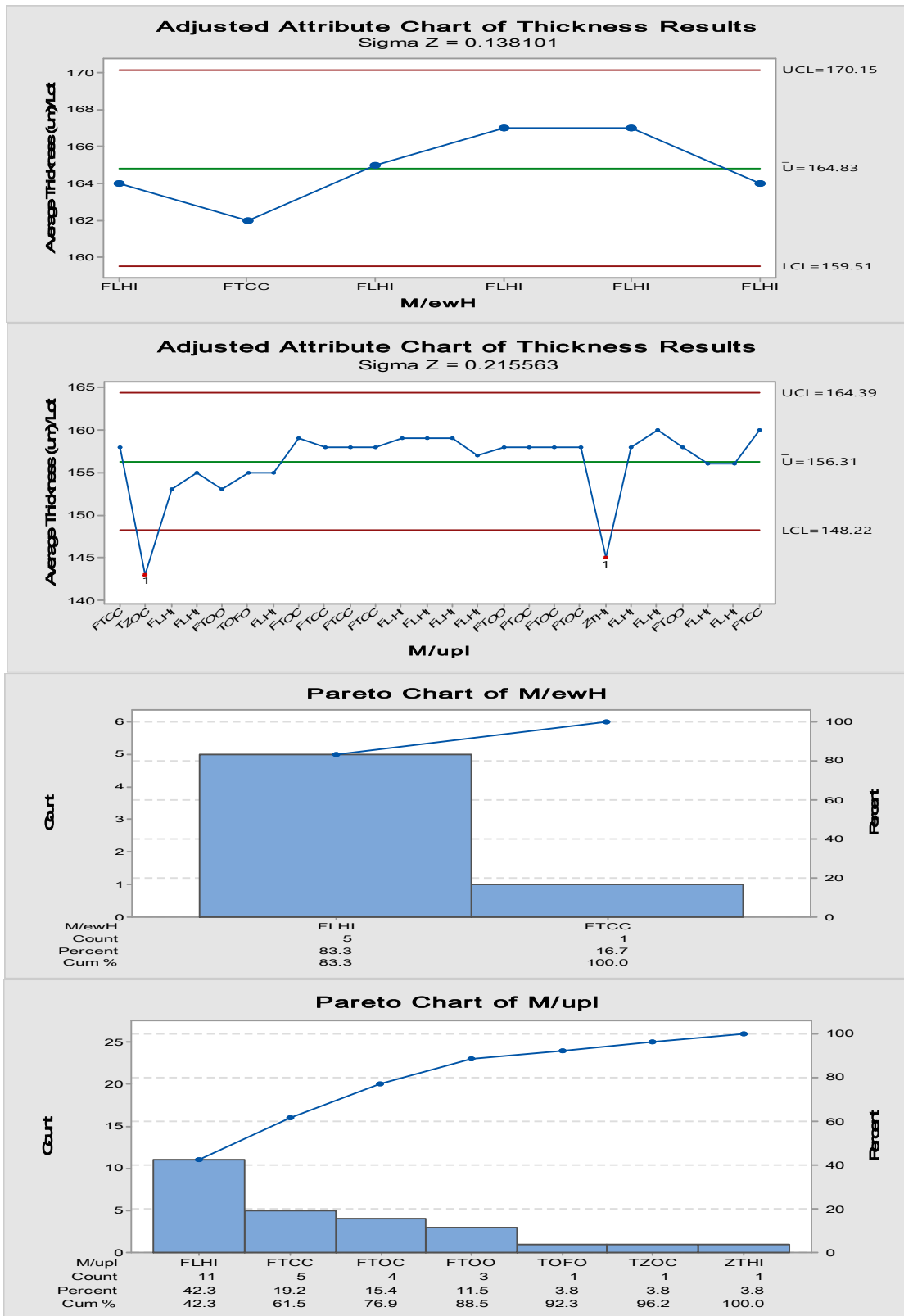


Figure 8. Shewhart charts and Pareto diagrams based on source manufacturers ewH and upl

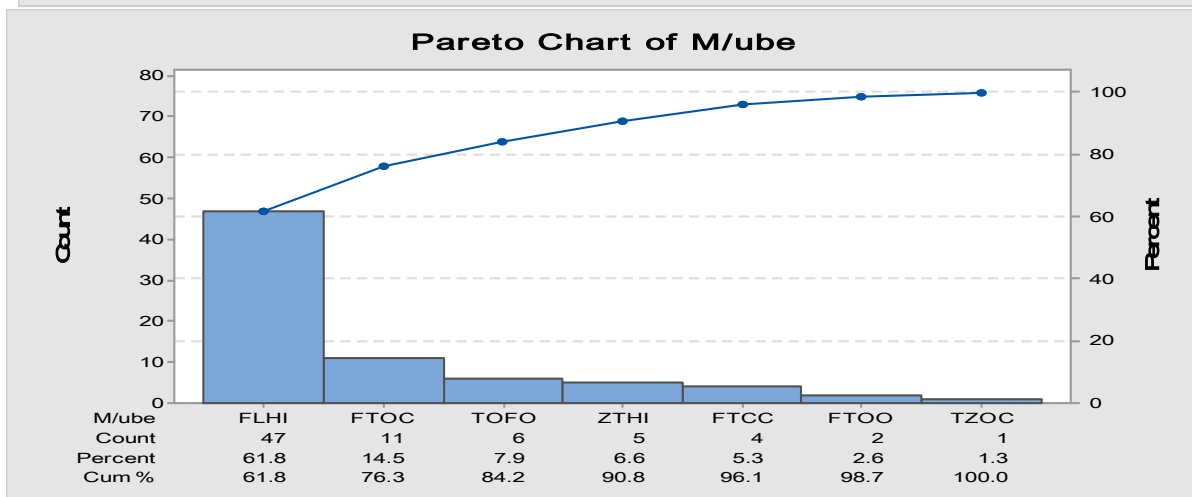
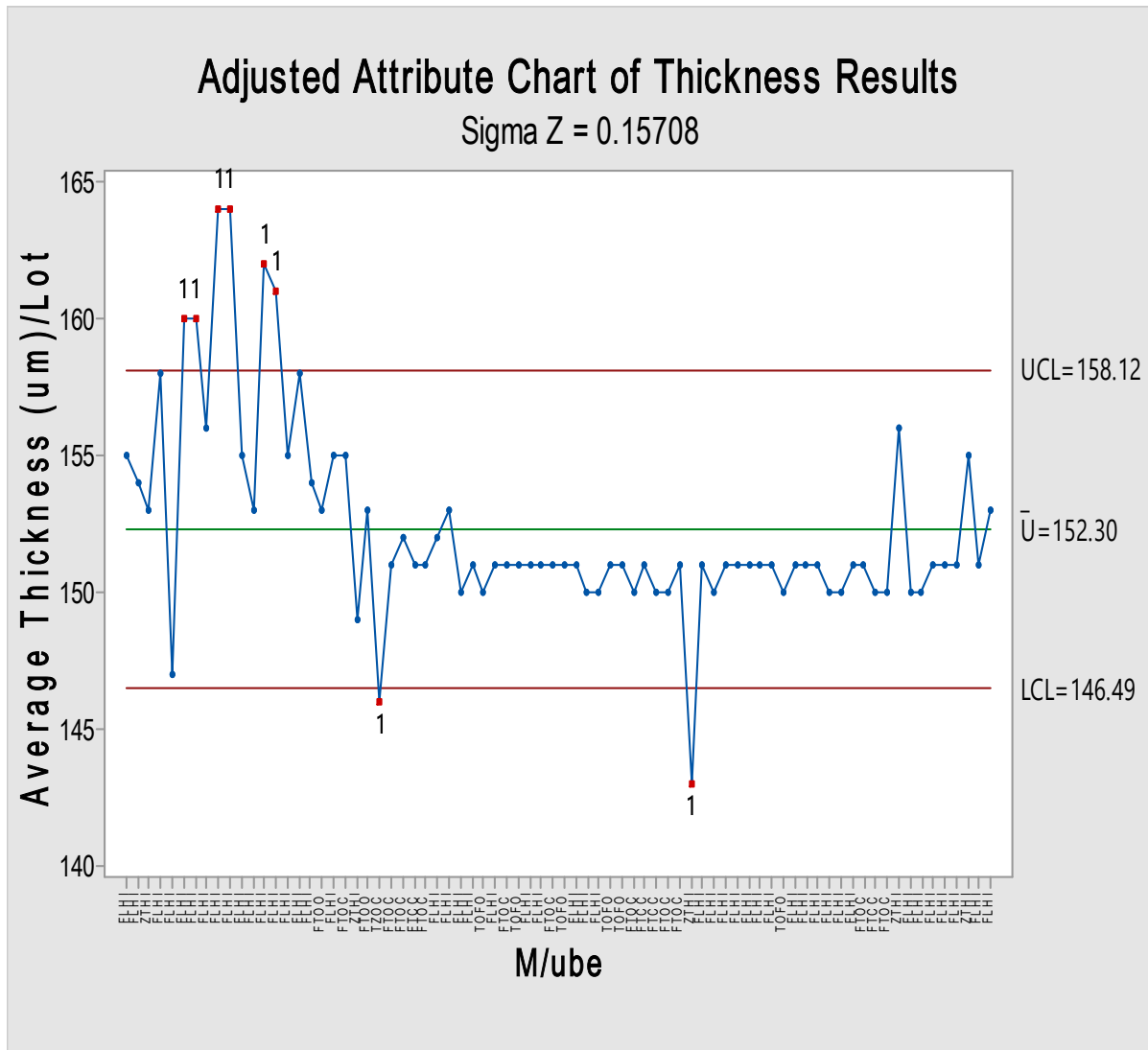


Figure 9. Shewhart charts and Pareto diagram based on source manufacturer ube

4. Discussion and Conclusion

The establishment of high reproducible quality standards is a critical aspect of the modern industrial business (Chesney, 2005; FDA, 2006; WHO, 2007; WHO, 2011). The high level of competition between organizations in the various fields - including the healthcare field - mandates rigorous control over the delivered service or product to satisfy customers' needs (Institute of Medicine, 1990). One of the critical aspects of quality inspection for the primary packaging components is the thickness of the containers that hold the contents of the product (Bora et al., 2014). The presented study simulates an investigational analysis towards supervision control over goods quality delivered to a warehouse from different vendors where they would be incorporated in further processes after the quality inspection phase.

4.1. The Principle theory Of Two-Dimensional GMM/Manufacturer-Based Segregation With Extension To Control Chart/Pareto Diagram For Data Analysis And Quality Improvement

When specific inspection properties are being expected for the incoming goods, it should normally meet certain acceptance criteria to enter the production phase and be subjected to further processing stages till the creation of the final product (Teasdale et al., 2017). These specification limits are mandatory values that should not be exceeded; otherwise, the shipment will not be accepted (Judson, 1976). However, as a part of quality improvement and risk mitigation of unwanted excursions, the provisional monitoring system would be desired, where early warning of drifting from the desired quality values could be spotted, identified and traced back to the possible root cause(s) (Eissa, 2018). When a relatively long-term database is collected over a specific period (such as a one-year record), it is essential to review the trending behavior of the recorded data and extract any suspicious unusual pattern. This was achieved using both the Shewhart chart and supported by a histogram and detailed in section (4.1.1). An approach that has been used previously in other work for improvement of quality and control of GMP behavior (Eissa and Abid, 2018). The Pareto analysis was used as a prioritization tool that helps the management in decision-making and resource allocation. Thus, it was used in each step and subgroup of the segregated datasets to bright up the main contributing factor(s) in the product trend output as described in subheading (4.1.2). GMM was approached as a mean of investigation for the data tendency for clustering to isolate non-homogenous processes (4.1.3) On the other hand, the conventional approach for the record investigation through data stratification based on the manufacturer (4.1.4). The last one would elucidate not only the supplier product fingerprint but also its quality and stability.

4.1.1. Overview of the trend of the quality criterion

Initial assessment of the overall pattern of data from the inspected parameter should be in control within CLs showing only common-cause variations (Henderson, 2011). This would be evident from the overall control chart. While histogram showed more than one hump shape interfering bar spreading, the process-behavior chart demonstrated two distinct patterns of the time-series arranged data. Similar SPC-derived outcome has been noted in other studies (Eissa, 2019c). However, if abnormal patterns or alarming points were found, assignable-sources of deviations should be investigated (Montgomery, 2013; Hou, 2016). The preliminary process-behavior chart showed an initial unstable section followed by an almost stable part of the chart. A brief look at the constructed histogram showed an unusual distribution that might be a mixture of at least two types of pattern data.

4.1.2. Role of Pareto analysis

Pareto diagrams are useful to spot the major contributors in any analysis in the present work. The focus on one or a few sources of variations such as products and/or manufacturers would help in resources management and prioritization (Harel et al., 2016). This will be helpful in focus auditing and follow-up of the suppliers to ensure harmonization and consistency of the product expected quality. For instance, containers of FLHI product were the most demanded item for the market need among the seven products with more than 60% share. One vendor "ube" has been identified as the main source of the packaging materials. Further research is mandatory to be executed on TZOC and ZTHI product types specifically because despite their very low probability of demand and arrival to the warehouse, they always showed persistent tendency to give lower-than-expected results. This investigation should include a thorough auditing plan, visit and follow up to correct and harmonize the quality inspection characteristics for the suppliers PM products.

4.1.3. Dimensions of data segregation and clustering

While Pareto graphs could provide a guide for data segregation based on the vendor of the packaging products, the GMM tool was found to be useful to separate dataset values based on their nature and tendency (Melchior and Goulding,

2018). Thus, stratification of the record could lead to a resolution into two interfering distributions. Further branching of data clustered values using Pareto/control chart combination analysis was useful in spotting product/manufacture patterns. This pattern on the turn will be very useful in the evaluation of the suppliers and to set Corrective Actions and Preventive Actions (CAPA) that ensure the dispatch and distribution of materials with the agreed acceptable specifications. For example, GMM demonstrated that the initial distribution (I) was rather chaotic with aberrant values on the lower side due to two types of packaging products (ZTHI and TZOC). While the ube manufacturer was the only supplier that could show desirable product quality with a narrow margin of variation, it was also found as contributing vendor in the other flattened spreading-type of data with the other two suppliers suggesting instability of the inspection characteristic for the predominant vendor, if it was compared with upl and ewH.

4.1.4. Preferential assessment of the suppliers

The previous analysis steps would pool into identifying the degree of compliance of each manufacturer to the in-house requirements of the healthcare firm (Schlegelmilch, 1998). The least frequent supplier viz ewH- with just six batches of PM - showed inspection characteristics with values that were strongly shifted to the upper specification limit and UCL exceeded this threshold. Despite no outliers were detected, this vendor should be investigated to improve the material quality with the regard of the home value. The dominant supplier showed initial shifting and strong fluctuations above the mean value which ceased in impedance towards a more stable thickness later, indicating an improvement in the supplier product manufacturing quality. However, this manufacturer demonstrated the highest rate of the excursions as overall efficiency. Further long-term monitoring is required to ensure reproducible stability for the supplier ube. Meanwhile, the manufacturer upl was positioned between both former vendors, with a relatively stable trend except for TZOC and ZTHI, which were common as exceptionally low thickness PMs. This supplier should be monitored with caution and audited to set an improvement plan for the product thickness around the base value. Finally, ube supplier showed dual pattern of initial instability followed by more stable trend, in contrast to the other two manufacturers. Nevertheless, ube demonstrated progressive improvement toward the target value. While the other less common vendors were more distant from the target value with a greater risk of an excursion beyond the limit, notably, the least common supplier ewH.

4.2. Final Conclusion

A consistent quality of the inspected quality characteristic is crucial in a competitive world that seeks excellence in the delivered product properties in the hand of the customers. The present case study was useful in the preferential selection and monitoring of the goods quality from different suppliers, which could provide a guide for improvements of the product inspection characteristics' and correction of any alarming deviations as early as possible before out-of-specifications cases would emerge and waste the normal business flow. In addition, this analysis is useful in the management of the suppliers' auditing activity where the firm could focus on conducting constructive audits with defective products and manufacturers to improve the qualities of their products. Two-dimensional stratification of the database was useful in identifying data clustering and pattern from which an investigation of the sources of the variability could be accomplished. Quantitative comparison and preferential selection between various manufacturers could be achieved, in addition to the determination of the relative stability and the quality of the imported inventory materials. The application of SPC tools that are normally used in industry were used herein to control material stock in warehouse & inventory management. Different techniques have been implemented. This study paves the way for adoption of unique quantitative metric for inventory weight value of the goods & will help in decision-making & forecasting concerning material stock mobility.

Legal/special permission

None was required as the current work system was established by the authors in a newly installed experimental facility.

Research and Publication Ethics

This research does not include any human or animal subject and comply with the ethics.

Contribution of Researchers

The present work was established by the authors only without any other contributors.

Acknowledgment

None to declare. The authors have supported the whole work including data collection.

Conflict of interest

The authors declare that there is not any conflict of interest.

References

- Bartholdi, J. J. & Hackman, S. T. (2014). *Warehouse & Distribution Science: Release 0.97*. Atlanta , USA, Supply Chain and Logistics Institute. Retrieved from: <https://www2.isye.gatech.edu/~jjb/wh/book/editions/wh-sci-0.96.pdf>
- Bienert, G. (2018). *Development and evaluation of product delivery strategies for demand-driven production-distribution systems* [Doctor of Philosophy, UNIVERSITY OF NEW SOUTH WALES]. unsworks.unsw.edu.au. Retrieved from <http://unsworks.unsw.edu.au/fapi/datastream/unsworks:54287/SOURCE02?view=true>
- Bora, A., Deshmukh, S., & Swain, K. (2014). Recent advances in semisolid dosage form. *International Journal of Pharmaceutical Sciences and Research*, 5(9), 3596. doi: 10.13040/IJPSR.0975-8232.5(9).3594-08
- Carey, R., Bhattacharyya, S., Kehl, S., Matukas, L., Pentella, M., Salfinger, M., & Schuetz, A. (2018). Implementing a Quality Management System in the Medical Microbiology Laboratory. *Clinical Microbiology Reviews*, 31(3). doi: <https://doi.org/10.1128/cmr.00062-17>. doi: 10.1128/CMR.00062-17
- Cato, W., & Mobley, R. (2002). *Computer-managed maintenance systems in process plants*. Gulf Pub. Co.: Houston, TX, USA.
- Celeux, G., & Govaert, G. (1992). A classification EM algorithm for clustering and two stochastic versions. *Computational statistics & Data analysis*, 14(3), 315-332. Retrieved from: [https://doi.org/10.1016/0167-9473\(92\)90042-E](https://doi.org/10.1016/0167-9473(92)90042-E)
- Center for Biologics Evaluation and Research. (2003). *Guidance for industry*. U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, Maryland. Retrieved from: http://blog-es.hygiene.com/1-por/docs/tech_lib/FDA_cGMP_Pharma.pdf
- Chambers, J. M., Cleveland, W. S., Kleiner, B., & Tukey, P. A. Graphical methods for data analysis. 1983. *Wadsworth & Brooks/Cole*: Duxbury, Boston, USA.
- Chesney, D. L. (2005). Management controls for GMP compliance. *Pharmaceutical Technology*, 4, 2005. Retrieved from: http://files.dvm360.com/alfresco_images/pharma/2014/08/22/b96657d2-d401-4d2e-a6ce-e3208b9d8ad7/article-155376.pdf
- Costantino, F., Di Gravio, G., Shaban, A., & Tronci, M. (2015). A real-time SPC inventory replenishment system to improve supply chain performances. *Expert Systems with Applications*, 42(3), 1665-1683. Retrieved from: <https://doi.org/10.1016/j.eswa.2014.09.028>
- Deelman, E., Singh, G., Su, M., Blythe, J., Gil, Y., & Kesselman, C. et al. (2005). Pegasus: A Framework for Mapping Complex Scientific Workflows onto Distributed Systems. *Scientific Programming*, 13(3), 219-237. doi: <https://doi.org/10.1155/2005/128026>.
- Eissa, M. (2019c). Application of Control Charts in Monitoring of Surgical Site Infection Trending Records Using Statistical Software. *Asian Journal Of Applied Sciences*, 12(2), 76-84. Retrieved from: <https://doi.org/10.3923/ajaps.2019.76.84>

Eissa, M. E. (2018). Role of Statistical Process Control of Pharmaceutical Product to Monitor Consistency of the Manufacturing Operation. *EC Pharmacology and Toxicology*, 6, 439-444. Retrieved from: <https://www.econicon.com/ecpt/pdf/ECPT-06-00182.pdf>

Eissa, M. E. (2019a). Monitoring of *Cryptosporidium* spp. Outbreaks Using Statistical Process Control Tools and Quantitative Risk Analysis Based on NORS Long-term Trending 9,1-7. doi: [10.3923/mj.2019.1.7](https://doi.org/10.3923/mj.2019.1.7)

Eissa, M. E. (2019b). Statistical Analysis Review and Lessons Learned from Recent Outbreak Trends of Highest Population Density States in USA: Massachusetts, New Jersey and Rhode Island. *Journal Of Food Chemistry & Nanotechnology*, 05(01). Retrieved from: <https://doi.org/10.17756/jfcn.2019-066>

Eissa, M., & Abid, A. (2018). Application of statistical process control for spotting compliance to good pharmaceutical practice. *Brazilian Journal Of Pharmaceutical Sciences*, 54(2). Retrieved from: <https://doi.org/10.1590/s2175-97902018000217499>

Food and Drug Administration (FDA). (2006). Guidance for industry: Quality systems approach to pharmaceutical cGMP regulations. *Pharmaceutical CGMPs*. Retrieved from: <https://www.fda.gov/media/71023/download>

Harel, Z., Silver, S., McQuillan, R., Weizman, A., Thomas, A., & Chertow, G. et al. (2016). How to Diagnose Solutions to a Quality of Care Problem. *Clinical Journal Of The American Society Of Nephrology*, 11(5), 901-907. <https://doi.org/10.2215/cjn.11481015>

Henderson, G. R. (2011). *Six Sigma quality improvement with MINITAB*. John Wiley & Sons: West Sussex. Retrieved from: https://books.google.com/eg/books?hl=en&lr=&id=EM5_VS7wEdUC&oi=fnd&pg=PP8&dq=Six+Sigma+quality+improvement+with+MINITAB+2011&ots=PtzzYZqbrO&sig=X-eiVE9Wvwx9di7JScDUV85SpXA&redir_esc=y#v=onepage&q=Six%20Sigma%20quality%20improvement%20with%20MINITAB%202011&f=false

Hou, S. W., Feng, S., & Wang, H. (2016). Intelligent process abnormal patterns recognition and diagnosis based on fuzzy logic. *Computational intelligence and neuroscience*, 2016. Retrieved from: <https://doi.org/10.1155/2016/8289508>

Huschka, K. (2009). *Using statistical process control to monitor inventory accuracy* (Doctoral dissertation, Kansas State University). Manhattan, Kan. Retrieved from: <http://hdl.handle.net/2097/1407>

Institute of Medicine (US) Committee to Design a Strategy for Quality Review and Assurance in Medicare, & Lohr, K. N. (Eds.). (1990). *Medicare: A Strategy for Quality Assurance*. National Academies Press (US). doi: <http://doi.10.17226/1547>

Iyer, H., & Prasad, S. (2007). *Statistical process control approach to reduce the bullwhip effect* (Doctoral dissertation, Massachusetts Institute of Technology). MIT Libraries. Retrieved from: <http://hdl.handle.net/1721.1/40105>

Jacoby, W. (1997). *Statistical graphics for univariate and bivariate data*. Sage Publications. Retrieved from ; https://books.google.com/eg/books?hl=en&lr=&id=-m7yE3E9iPkC&oi=fnd&pg=PR5&dq=Statistical+Graphics+for+Univariate+and+Bivariate+Data&ots=71HBGNTU_v&sig=Y2glCSHp2k6rr-C3aSfKh5eZCOs&redir_esc=y#v=onepage&q=Statistical%20Graphics%20for%20Univariate%20and%20Bivariate%20Data&f=false

Jones, G., & Govindaraju, K. (2001). A GRAPHICAL METHOD FOR CHECKING ATTRIBUTE CONTROL CHART ASSUMPTIONS. *Quality Engineering*, 13(1), 19-26. <https://doi.org/10.1080/08982110108918620>

Judson, L. V. H. (1976). *Weights and measures standards of the United States: a brief history* (Vol. 447). Department of Commerce, National Bureau of Standards, USA. Retrieved from:

https://books.google.com/books?hl=en&lr=&id=gCWCvYlgRcC&oi=fnd&pg=PA1&dq=Weights+and+measure+standards+of+the+United+States:+a+brief+history&ots=bq8T07mxLH&sig=WDIE2ZXe4P5Zu-VUDONi55P8hws&redir_esc=y#v=onepage&q=Weights%20and%20measures%20standards%20of%20the%20United%20States%3A%20a%20brief%20history&f=false

Juran, J. M. (1960). Pareto, Lorenz, Cournot, Bernouli, Juran and others. *Industrial Quality-Control* 17(4),: 25. Retrieved from: [https://books.google.com/books?hl=en&lr=&id=v_fprq_XtFAC&oi=fnd&pg=PA47&dq=Juran,+J.+M.+\(1960\).+Pareto,+Lorenz,+Cournot.+Bernoulli,+Juran+and+others,+op.+cit,+25.&ots=uC_pB-UJnc&sig=tPoGeCYpp-dwFKItfVVti35mPnE&redir_esc=y#v=onepage&q=Juran%2C%20J.%20M.%20\(1960\).%20Pareto%2C%20Lorenz%2C%20Cournot.%20Bernoulli%2C%20Juran%20and%20others%2C%20op.%20cit%2C%2025.&f=false](https://books.google.com/books?hl=en&lr=&id=v_fprq_XtFAC&oi=fnd&pg=PA47&dq=Juran,+J.+M.+(1960).+Pareto,+Lorenz,+Cournot.+Bernoulli,+Juran+and+others,+op.+cit,+25.&ots=uC_pB-UJnc&sig=tPoGeCYpp-dwFKItfVVti35mPnE&redir_esc=y#v=onepage&q=Juran%2C%20J.%20M.%20(1960).%20Pareto%2C%20Lorenz%2C%20Cournot.%20Bernoulli%2C%20Juran%20and%20others%2C%20op.%20cit%2C%2025.&f=false)

Kumar, D. (2006). *Six sigma best practices: a guide to business process excellence for diverse industries*. J. Ross Publishing: USA. Retrieved from: https://books.google.com/books?hl=en&lr=&id=IB0rfMTOkqYC&oi=fnd&pg=PA1&dq=Six+sigma+best+practices:+a+guide+to+business+process+excellence+for+diverse+industries&ots=gdKICfnZfU&sig=9azHwRLQAqtDfcWhlRasRk5IkU&redir_esc=y#v=onepage&q=Six%20sigma%20best%20practices%3A%20a%20guide%20to%20business%20process%20excellence%20for%20diverse%20industries&f=false

Laney, D. B. (2002). Improved control charts for attributes. *Quality Engineering*, 14(4), 531-537. Retrieved from: <https://doi.org/10.1081/QEN-120003555>

Lightfoot, P., & Kauffman, R. G. (2003). Controlling warehouse performance with statistical process methods. *Journal of Public Procurement*, 3(1), 29. Retrieved from: https://www.researchgate.net/profile/Ralph_Kauffman2/publication/265748593_CONTROLLING_WAREHOUSE_PERFORMANCE_WITH_STATISTICAL_PROCESS_METHODS/links/55d9743d08aeb38e8a87d30f/CONTROLLING-WAREHOUSE-PERFORMANCE-WITH-STATISTICAL-PROCESS-METHODS.pdf

McLachlan, G., & Peel, D. (2006). *Finite mixture models*. John Wiley & Sons: NY, USA. Retrieved from: https://books.google.com/books?hl=en&lr=&id=c2_fAox0DQoC&oi=fnd&pg=PR7&dq=Finite+Mixture+Models+2000&ots=ItWC1V88iC&sig=jesok4wEt6IwQr40nfyOmkVIV1c&redir_esc=y#v=onepage&q=Finite%20Mixture%20Models%202000&f=false

Melchior, P., & Goulding, A. D. (2018). Filling the gaps: Gaussian mixture models from noisy, truncated or incomplete samples. *Astronomy and computing*, 25, 183-194. Retrieved from: <https://doi.org/10.1016/j.ascom.2018.09.013>

Montgomery, D. (2013). *Introduction to statistical quality control*. Wiley Global Education: Arizona State University

Moraru, L., Moldovanu, S., Dimitrievici, L., Dey, N., Ashour, A., & Shi, F. et al. (2019). Gaussian mixture model for texture characterization with application to brain DTI images. *Journal Of Advanced Research*, 16, 15-23. Retrieved from: <https://doi.org/10.1016/j.jare.2019.01.001>

Muller, M. (2019). *Essentials of inventory management*. HarperCollins Leadership: Australia. Retrieved from: https://books.google.com/books?hl=en&lr=&id=R_JWDwAAQBAJ&oi=fnd&pg=PP1&dq=Essentials+of+inventory+management&ots=7yVfMc0H3E&sig=QYB7pGA61aw9NgYFF-GgxpA3xvA&redir_esc=y#v=onepage&q=Essentials%20of%20inventory%20management&f=false

National Research Council. (2000). *Surviving supply chain integration: Strategies for small manufacturers*. National Academies Press: Washington, DC. Retrieved from: https://books.google.com/books?hl=en&lr=&id=GupuAgAAQBAJ&oi=fnd&pg=PR16&dq=Surviving+supply+chain+integration:+strategies+for+small+manufacturers+2000&ots=3wi6TDgUOH&sig=OTh8J3MMZ3HWuvxVXAdEvcMROho&redir_esc=y#v=onepage&q=Surviving%20supply%20chain%20integration%3A%20strategies%20for%20small%20manufacturers%202000&f=false

- Oliveira, P. M., Novais, P., & Reis, L. P. (Eds.). (2019). *Progress in Artificial Intelligence: 19th EPIA Conference on Artificial Intelligence, EPIA 2019, Vila Real, Portugal, September 3–6, 2019, Proceedings*, 2(11805). Springer Nature. Retrieved from: https://books.google.com.eg/books?hl=en&lr=&id=mButDwAAQBAJ&oi=fnd&pg=PR5&dq=Progress+in+Artificial+Intelligence+2019+Oliveira&ots=avq0XX4N2m&sig=KPJsiEkL2MD3RTrBpeT7iKoLOBw&redir_esc=y#v=onepage&q=Progress%20in%20Artificial%20Intelligence%202019%20Oliveira&f=false
- Pfohl, H. C., Cullmann, O., & Stolzle, W. (1999). Inventory management with statistical process control: simulation and evaluation. *Journal of Business Logistics*, 20(1), 101-120. Retrieved from: <https://search.proquest.com/openview/54aca944437505ae5a3757380de04aea/1?pq-origsite=gscholar&cbl=36584>
- Pyzdek, T., & Keller, P. (2009). *The six sigma handbook*. McGraw-Hill Professional: NY, USA.
- Rachmania, I. N., Basri, M. H. (2013). *Pharmaceutical inventory management issues in hospital supply chains*. *Management*, 3(1):1-5. doi: <http://DOI: 10.5923/j.mm.20130301.01>
- Reynolds, D. A., & Rose, R. C. (1995). Robust text-independent speaker identification using Gaussian mixture speaker models. *IEEE transactions on speech and audio processing*, 3(1), 72-83. doi: <http://doi.10.1109/89.365379>
- Ryan, T. (2013). *Statistical methods for quality improvement*. Wiley: Hoboken, NJ, USA.
- Ryan, Th. P. (2000). *Statistical Methods for Quality Improvement*, (2nd ed.). Wiley Series in probability and statistics, John Wiley & Sons: NY, USA.
- Schlegelmilch, B. B. (1998). *Marketing ethics: An international perspective*. Cengage Learning EMEA, Berkshire House: London, UK.
- Sokal, R. R. (1995). *The principles and practice of statistics in biological research. Biometry*, (3rd ed, pp. 451-554). Freeman, New York, USA.
- Teasdale, A., Elder, D., & Nims, R. W. (2017). *ICH Quality Guidelines*. John Wiley & Sons, Inc., Hoboken, NJ, USA.
- Thompson, J. (2011). *Empirical model building*. John Wiley & Sons: NJ, USA.
- Tomassone, R., Dervin, C., & Masson, J. P. (1993). *Biométrie. Modélisation de phénomènes biologiques* (pp. 553-p). Elsevier Mason SAS: Paris, France.
- Wilkinson, L. (1999). *The Grammar of Graphics*. Springer Verlag: NY, USA.
- World Health Organization (WHO). (2007). *Quality assurance of pharmaceuticals: A compendium of guidelines and related materials. Good manufacturing practices and inspection* (Vol. 2). World Health Organization.
- World Health Organization (WHO). (2011). *Laboratory quality management system: handbook*. World Health Organization. Retrieved from: https://apps.who.int/iris/bitstream/handle/10665/44665/9789244548271_rus.pdf