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RESEARCH ARTICLE

USING MEASUREMENT SYSTEM ANALYSIS AND STATISTICAL PROCESS CONTROL FOR MONITORING AND REDUCING VARIATION IN THE PROCESS

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ABSTRACT

Measurement System Analysis (MSA) is used to determine the amount of variation due to Measurement System (MS) in the total variation of the process. It also assesses the effects of measurement error of the analytical instrument or by the operators/appraisers in the process. MSA consists of methods such as Gage Repeatability & Reproducibility (GR&R), Bias and Stability to assess the Measurement System. After MSA is performed successfully, the next step is Statistical Process Control (SPC). In SPC, Control Charts are most commonly used to determine whether the process is in control and stable. Control Charts works by collecting the data from the analysis of samples and arranging the data in the graphical manner to visually assess the stability of the process. Along with the Control Charts, the Process Capability Indices can also be calculated to determine the reliability of the process in the future.

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INTRODUCTION

MSA and SPC are the two approaches that can be used together to minimize the error/variation in the Measurement System (MS) and the Process. Both approaches together ensure the Process is in control and the data from the results are reliable. MSA is described as a mathematical and experimental technique to determining the amount of variation that exists within a measurement process and minimizing the elements that contribute to process variation that are not really caused by the measurement system. MSA evaluates the Measurement System's accuracy, precision, and stability to determine whether it is suitable for use. To assure the integrity of data, MSA is becoming more important to assess the test technique, measuring equipment, and complete measurement process (Cagnazzo, 2010) In understanding and managing measurement error, MSA plays a very vital role for process improvement. MSA includes Gage Repeatability & Reproducibility (GR&R), Bias and Stability methods to evaluate measurement data. Statistical process control (SPC) is defined by the American Society for Quality as "the application of statistical techniques to control a process." The basic theory of statistical process control was developed in the late 1920s by Dr. Walter Shewhart, a statistician at the AT&T Bell Laboratories in the USA, and was popularized worldwide by Dr. W Edwards Deming (Benneyan, 2003).

SPC tools and procedures can help you monitor process behavior, discover issues in internal systems, and find solutions for production issues. SPC is also useful in demonstrating that a process is capable of consistently delivering what the customer wants. Control charts are most commonly used in SPC method. In Control Chart, the control limits i.e., Upper Control Limit (UCL) and Lower Control Limit (LCL) and center line are set. These values in control chart are depending on the data which we get from the analysis of samples in the process. The sorts of causes of variation, such as Common Cause Variation and Special Cause Variation, may also be determined using control charts. In addition, Process Capability Indices (such as Cp, Cpm and Cpk) are used to assess the reliability of the data. PCI determines the capability of process to produce the desire outcomes.

Measurement System Analysis: MSA is the ability to recognize and manage measurement error, which is a critical function for process improvement. The measurement part, measuring method, measurement process, measurement equipment, and reference standard and measurement environment make up the measurement system (MS).(1) The measurement system in any pharmaceutical process should be accurate enough to make the right judgement of a product and process quality. Thus, error in the measurement of any process indicates problems related to the measurement instrument. Any process' measurement should be trustworthy and accurate, and errors should be avoided in any way possible. Components in the MSA consist of Gage Repeatability and Reproducibility (GRR), Bias and Stability.(3)

Bias (Accuracy): A systematic divergence from the true master value of a measurement result is known as bias (i.e., Accuracy of a measurement). Bias is defined as the difference between an observed measurement and a genuine value or reference value obtained from a master or gold standard, or from another measuring process proved to produce reliable results. It's either due to a human error or an instrument error that adds (or subtracts) a constant value to each reading (Senvar, 2010).

Stability: Stability – is the total variability in a measurement recorded over a lengthy period of time when measuring the same feature using the same master or reference value. It assists in determining varying degrees of variability in various regimes. Operator unreliability, a lack of conventional operating procedures, warm-up effects, and environmental factors can all wreak havoc on stability. It determines how much prejudice has evolved over time (Senvar, 2010).

Gage R&R Study: A faulty measuring system might render data useless and prevent process improvement. A statistical approach for determining the amount of variation existing in the measuring system arising from the measurement equipment and operator is the Gage R&R study, which is part of MSA (Deshpande, 2014; Deshpande, 2020) Gage R&R is required to determine the overall observed variability as a result of the instrument. It helps to separate the system's components of variability. Determine whether the instrument is appropriate or capable for the task at hand. The Repeatability and Reproducibility are the two important constituents of Gage R&R (as name itself consist of Repeatability and Reproducibility). The term "Repeatability" refers to a gage's ability to record the same observed value when measuring the same component several times under ideal conditions. That means the ability of the same appraiser to measure the same part/sample several times with the same measuring instrument and come up with the same result. “Reproducibility” is a term that describes how parts vary when measured under different situations, for as by different operators or during different time periods. Reproducibility determines if many appraisers can use the same measuring instrument to measure the same part/sample and arrive at the same value.[4] In GRR, “Repeatability” can also be termed as Variation from Instrument or Equipmenti.e., Equipment Variation (EV). Same for “Reproducibility”, it can also be termed as Variation among Operators or Appraisers i.e., Appraiser Variation (AV).[4] The Total Variation in the Measurement of the process is the sum of the Process Variation and Measurement System Variation.

$$\sigma_{TV}^2 = \sigma_{PV}^2 + \sigma_{GRR}^2 \quad (1)$$

Similarly, the GRR (σ2GRR) is the sum of Equipment Variation (EV) and Appraiser Variation (AV).

$$\sigma_{GRR}^2 = \sigma_{EV}^2 + \sigma_{AV}^2 \quad (2)$$

In conclusion, GRR tells us about the total variation in the measurements contributed by the Measurement System (MS) towards the Total Variation (TV). The variation of the MS (σ2GRR) should be less compared to the Process Variation (PV) (Deshpande, 2014; Deshpande, 2020) This will confirm that the MS is truly reliable for the analysis of the sample in the process. If this happens then operating personnel can take the correct decision regarding stability of the process.

This leads to the desired output from the process, since operator can intervene or make changes in the process based on the reliable measurements. Therefore, it is very convenient to conduct MSA study in the form of GRR in the Pharmaceutical Manufacturing Process for conducting Quality-By-Design approach for the quality product with minimum variation (Deshpande, 2014) There are two ways to approach GRR studies viz. Crossed GRR and ANOVA GRR. However, ANOVA GRR method is mostly preferred because the ANOVA table would indicate whether a variation from a specific source is significant or not based on the p-value (Deshpande, 2014; Deshpande, 2020) (Amol Deshpande et al. 2014 and Atharva Deshpande et al. 2020). After conducting a successful MSA method to ensure the reliability of the Measurement System (MS), the next step is the SPC.

Statistical Process Control: Walter A. Shewhart introduced the concept of control chart (or process behavior chart) on May 16, 1924, which is currently known as Statistical process control. SPC is defined by the American Society for Quality as “the application of statistical techniques to control a process.” Basically, SPC tools are used to control or reduce the variation in the process and thus, it confirms that the variation from the process is within specified limits (Pawlicki, 2008; Best, 2006). In any process variation is inevitable (Harpreet, 2016). It is impossible to completely eliminate the variation in the any process. But variation can be minimized to the extent possible using SPC methods. SPC uses statistics and displays the results in the visual graphical presentation which helps the operator to keep an eye on any variation in the process (Harpreet, 2016; Cheung, 2012) The main aim of the SPC is to minimize variation in the process and consequently improving the quality of the products (Harpreet, 2016; Eissa, 2018; Subbulakshmi, 2017) As a result, SPC is very powerful tool for ensuring process stability along with the use of DMAIC (Define, Measure, Analyze, Improve and Control) quality improvement model (Harpreet, 2016)The measurements from the analysis of the quality parameters of the process are used as the data for performing the SPC (Montgomery, 2009) The variation in the process should be random and generally Normally Distributed. For the normal distribution of the random variation, the process should be stable. If the process is stable enough, the variation is predictable and it is easier to plot graphs for SPC (Benneyan, 2003).

SPC’s seven major tools are (Montgomery, 2009):

- Histogram or stem-and-leaf plot
- Check sheet
- Pareto chart
- Cause-and-effect diagram
- Defect concentration diagram
- Scatter diagram
- Control chart

Common and Special Cause Variation: The SPC broadly classifies variation based on the types of cause of variation – Common Cause Variations and Special Cause Variations. The term "Common Cause Variation" is used in SPC theory to refer to the natural variation that occurs in a process on a regular basis.This is the variance that the underlying statistical distribution predicts would occur if its parameters remain constant across time (Benneyan, 2003). It is also known as “Chance Cause Variation” since these are natural variation and is the result of a number of tiny, mostly inevitable factors (Montgomery, 2009) On the contrary, the term “Special Cause Variation” is used in the SPC theory to refer to unnatural variation owing to events, changes, or conditions that were not previously usual or inherent in the normal process (Benneyan, 2003) It is also known as “Assignable Cause Variation” since this type of variation is unnatural and occasionally present due to the improperly adjusted or controlled machines, operator errors, or defective raw material (Montgomery, 2009) Processes with only common cause variation are considered to be stable, predictable, and said to be “in statistical control”, whereas processes which exhibits special cause variations are unstable, unpredictable and said to be “out of statistical control”.(Benneyan, 2003) The efforts are always to eliminate the “Special Cause Variation” in the process, if detected. If there is a particular cause variation, the operator examines – what went wrong? Accordingly, operator intervenes in the process or corrects the faulty parts and brings the process in statistical control (Montgomery, 2009) Out of these seven tools, Control Chart is one of the most important and widely used tool. In this article, Control Charts and their applications are briefly discussed.

Control Charts: Shewhart Charts are known as control charts. Measurements from the process are used as data points in the control chart. These data points are graphically displayed and organized in a

graphical format. The ongoing process may be clearly deduced from these shown graphs. From these plotted graphs one can easily interprets the on-going process (Cheung, 2012) Basically, Control Charts consists of the central solid line as well as two horizontal parallel dotted lines, one above and one below the centerline. The upper dotted horizontal line above the centerline is the Upper Control Limit (UCL) and the lower dotted horizontal line below the centerline is the Lower Control Limit (LCL). These three lines viz. Centerline, UCL and LCL are parallel to the X-axis. This control limits i.e., UCL and LCL are set to check whether the process is in control or not. That is to say, the data points should fall between UCL and LCL which shows that the process is in statistical control. Thorough investigation is needed, if the data points fall outside the control limits (i.e., UCL and LCL), which signifies that the process is out of statistical control. Generally, the control limits are set at ± 3SD from centerline (Montgomery, 2009; Shah, 2010). However, setting control limits is a very important task (Benneyan, 2003). If it not properly set the chances of errors i.e. Type I and Type II error are very high. Type I error occurs when the process is mistakenly inferred as out of control but, in reality, it is not. Thus, Type I error is also referred to as False Positives indication. On the contrary, Type II error occurs when the process is inferred as in control, but it is really out of control. The special cause or out of control data points occurs as the time passes on, due to the inherent natural variation in the process. But, it can be mistakenly concluded as out of control process (i.e. Type I error). Also, if the data points follow a trend i.e., a non-randomness and falls within the control limits but above or below the centerline, then the process is really out of control, even if it looks in control (i.e., Type II error).[12] Therefore, if the limits are set too narrow, there is a high risk of Type I error whereas if the limits are set too wide, there is a high risk of Type II error (Benneyan, 2003).

Types of Control Charts: The Control Charts are classified into two categories depending upon their use: Variable Control Chart and Attribute Control Chart.

Variable Control Charts: A variable is a single quantifiable qualitative attribute, such as a dimension, weight, or volume.[12,13] When working with a variable quality characteristic, it's common to need to keep track of both the mean value and the variability of the quality characteristic. The control chart for means is commonly used to regulate the process average or mean quality level (i.e., X-bar Chart). A control chart for the standard deviation, known as the s control chart, or a control chart for the range, known as the R control chart, can be used to monitor process variability. The R chart is more common. Typically, each quality attribute of importance is represented by a distinct R chart, along with its X-bar chart.

Attribute Control Charts: Many quality qualities are difficult to express through measurements. The terms conforming and nonconforming are frequently used to distinguish between these defective and non-defective product groups. This sort of quality feature is referred to as an attribute. The control chart for fraction nonconforming, or p chart, is the first of these, and it refers to the proportion of nonconforming or faulty product generated by a manufacturing process. The control chart for nonconformities, or c chart deals with the number of faults or nonconformities observed rather than the proportion nonconforming is more convenient. The u chart is a control chart for nonconformities per unit that is used when the average number of nonconformities per unit provides a more practical foundation for process control (Montgomery, 2009).

Process Capability Indices: Now, the question here is, whether the current production method is indeed capable of delivering high-quality items with little variance. To answer this question, Process Capability studies are very important aspects. Process capability studies determine if a process can produce almost any conforming product.[14] Process capability can be measured in terms of percent nonconforming or natural spread compared to specification spread. These values which we get from calculation are termed as Process Capability Indices.

Process Capability Indices are a way to measure how effectively a process can create a product that is acceptable. The following terms - Cp, Cpk Cpm and Cpmk are known as Process Capability Indices.(M. Suozzi, 1990 and Wooluru et al. 2014). The statistical control of the process i.e. SPC step is required for the calculation of predicted process capability indices (Winton Don, 1999) Cp is a process capability index that relates the natural process spread to the specification (tolerance) spread to determine the process's potential performance. Cpk is a process capability index that accounts for a change in the process mean towards either the upper or lower specification limit to determine real performance (Winton Don, 1999). Cpm is concerned with how well the process mean matches the process target, which may or may not be in the middle of the specification boundaries. Cpmk calculates process capacity around a target (T), adjusts for a process mean that is off-center, and assumes that process output is roughly normally distributed.

Conclusion

The MSA tool is used to reduce inaccuracy from the Measurement System (MS) to the Total Variation (TV). MSA certifies that the Measurement System is capable of providing accurate sample measurements. The next phase is SPC, which comes after a successful implementation of MSA in the form of Gage R&R. SPC is concerned with reducing variability in the process. SPC may be used to an on-line process, assuring process control. Process Capability Indices also provide a clear picture of the process's ability to remain stable throughout time.

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