INTERNATIONAL JOURNAL OF RESEARCH IN AERONAUTICAL AND MECHANICAL ENGINEERING

ISSN (ONLINE): 2321-3051

Vol.4 Issue 4,

April 2016

Pgs: 85-97

Statistical Process Control and Six Sigma an Integrated approach to Improve Process in Medical Device Industry

Mr. Akshay Parab[1], Prof. S.N.Teli[2] and Prof. M.M.Jagtap[3]

[1]PG Scholar, Mechanical Engineering Department, Saraswati College of Engineering, Kharghar
[2]Dean Administrator and Associate Professor, Mechanical Engineering Department, Saraswati College of Engineering, Kharghar
[3]Assistant Professor, Mechanical Engineering Department, Saraswati College of Engineering,Kharghar

Abstract: Process Capability considering different policies done in previous work shows that Statistical Process Control is deployed to find Capability of Machines. Different methods can be used for process improvements. In present case DMAIC methodology combined with different SPC tools is used to identify and improve the existing process in medical devices industry. In previous work. Lots of effort utilized in identifying process capability of machines and improving processes in different industries. In this work with statistical process control combined with six sigma tools helps in solving problem related with rejection rate and proves that this methodology is good in process improvement. This research methodology is scientific and applied by combining various process improvement tools. Therefore, it is very easy to apply and improving process with management techniques.

1. Introduction

Medical device regulations require valid statistical techniques to verify process capability. This means you need to understand them and be ready for questions from FDA investigators and auditors.

A key outcome of Medical validation studies is proving equipment, instruments and processes that are involved in the manufacture or testing of regulated materials are fit for purpose. Fit for purpose means that a system consistently performs the process it was designed to do when operated within

normal limits. It can be quantified statistically by determining and measuring parameters with respect to acceptance limits.

Manufacturing processes for medical devices involve statistical methods. Process capability analysis examines the inherent variability in a process including the statistical distribution of the process output. When the measurement uses variables data, process variability is the "spread" of a process in statistical control. When the measurement involves attributes data, process capability is often the proportion of nonconforming units.

Data collection and analysis have always played a vital role in manufacturing and with strict regulations and legislation becoming commonplace; manufacturers are required to look at ways of improving their production processes to ensure increased customer satisfaction, operational efficiency and product quality.

Continuous improvement of Medical Devices Industry requires the measuring and understanding of process variation. It is important to eliminate extraneous process variation wherever possible, while moving well-defined metrics toward their target values.

Within this context, statistical process control (SPC) tools and techniques are very useful tools for studying important process variables and identifying quality improvements or quality deterioration. This method has been adopted since 1940s in the industrial area. The use of this method has a significant improvement towards the quality characteristic of manufactured products in industrialized countries, such as Japan and United States. The idea of this method is to thoroughly control production process of products/services such that fit the customer satisfaction. The manufactured products should have fitness values for use, such as well-performed, reliable, durable, easy to repair, good visual appearance, has outstanding function, good reputation, and satisfy the expected requirements.

Process capability analyses (PCA) occupy important places in quality and process improvement initiatives. As a fundamental technique in any production, quality and process improvement efforts, PCA is used to improve processes, products or services to achieve higher levels of customer satisfaction. In order to measure process capability numerically, process capability indices (PCIs) have been developed.

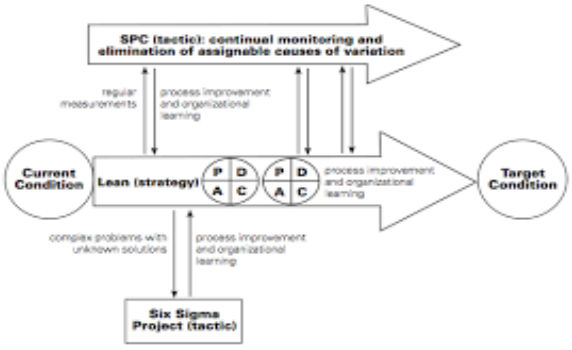

Figure1 Combine role of SPC tools and Six Sigma to achieve target Condition

Figure 1 shows the role of SPC tools and Six Sigma in process improvement.

2. Methodology

The DMAIC methodology should be used when a product or process is in existence and is not meeting customer specification or is not performing adequately. In this project, the same methodology is used.

- Define the project goals and customer (internal and external) deliverables.
- Measure the process to determine current performance.
- Analyse and determine the root cause for the defects.
- Control future process performance.

Objective of study

- Predicting the extent of variability that process will exhibit.
- To predict current and future capability of the process to produce product within specification in the company.
- To investigate the product produced by the company meet the customer's Specification.
- Reducing the variability of the manufacturing process.
- Planning the interrelationship of sequential process.
- To improve internal customer satisfaction.

Figure2 functional relationship of Six Sigma and SPC

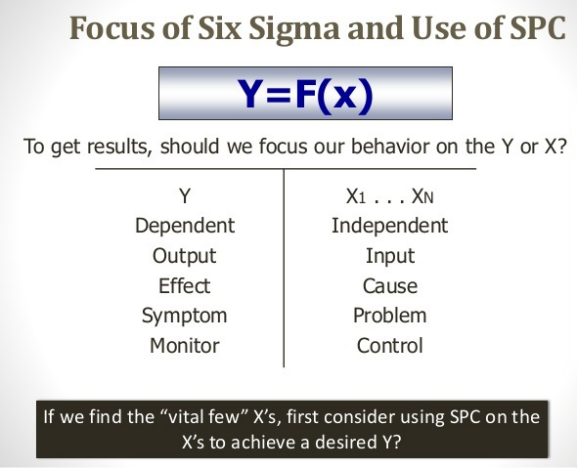

Figure 2 shows the functional relationship between SPC and Six Sigma and their dependencies on each other.

3. Literature Review

Sachin Prakash Wanare, Prof. Mangesh V. Gudadhe

Capability analysis helps to determine the ability for manufacturing between tolerance limits and engineering specifications. Capability analysis can be applied not only to production period but also to a machine or machine tool. Capability analysis gives the information about changes and tendencies of the system during production. It is used to determine the system tendencies between tolerance limits.

As it can be seen from the study accomplished, the process control and capability method is more effective for determining the quality problems and solving them in small and medium sized companies that manufacture parts by machining and develop more efficient processes in order to survive in the competitive market. Thereby, correct understanding of the components of variables, definition of factors causing variations and keeping them under control is all important for small sized companies.

Sarina Abdul Halim Lim and Jiju Antony

The objective of this paper is to investigate SPC implementation in the food industry setting by applying systematic literature review, and to explore the extensiveness of SPC application in the food industry. This review identified 41 studies published between 1980 and 2012, depicting evidence of SPC application sparsely spread throughout the industry and a need to pursue more research in this topic.

Determining CSF for SPC implementation is crucial. However CSFs themselves does not depict a coherent implementation framework where they are required to be integrated into an implementation plan. A viable framework for SPC implementation should able to provide a framework that emphasised CSF and features of a good framework sufficiently not only in the context of the technique (SPC), but also in the context of the industry. Based on the literature review, there is no useful and practical guideline available in the context of the food industry.

Khaled N. El-Hashmi and Omar K. Gnieber

In this study it has been shown that statistical process control and process capability analysis as a part of six sigma project can be applied effectively in healthcare service. Using real data based on the turnaround time of CBC test in BMC clinical laboratory, it has been first monitored the TAT using control charts, then followed by capability analysis to estimate the proportion of out-of-specification TAT and that will lead to calculate the DPMO and sigma level. However, the conclusion is that the service of an observed clinical laboratory of BMC is ineffective process that cannot reduce the time form the receipt of test orders at reception of laboratory to the release of test results. In other words, the BMC clinical laboratory produce quality characteristic (i.e. TAT) that cannot meet the specifications. So the two-way improvement solutions are required first to improve the process average and then reduce process spread.

J. Cordeiro1, J. G. Requeijo

The development of a statistical control methodology appropriated to the existence of significant process autocorrelation, reveals a crucial importance, since it avoids possible analysis errors. If the autocorrelation is not considered, some mistakes may occur, namely: 1) Consider a stable process, when several special causes of variation are present, which corresponds to a non-stable process; 2) Consider a process out of statistical control, when it is actually stable (increase of false alarms); 3) Incorrect estimate of the process parameters; 4) Proceed to rough and/or incorrect analysis of the process capability; 5) loss of resources by a unnecessary intervention on the productive process, in order to solve problems which are not real (false alarms).

Hairulliza Mohamad Judi, RuzzakiahJenal and DevendranGenasan

The study finds that the motivating factors for these companies to apply quality control come internally from the management and parent company or externally from customer. SPC and acceptance sampling are used widely by the companies. Six sigma, DOE, Taguchi methods, and capability studies are left behind from being used in these four industries, due to lack of knowledge in the technique. The selection of quality control technique in these companies is influenced by

three factors: ease of use of the technique; ability to measure product specification fulfillment; and ability to improve critical quality and productivity problem.

Neal B. Gallagher and Barry M. Wise

The success of developing the monitoring strategy depended on the availability of long term data. The etch process is non-stationary and contains large amounts of normal variance. Testing monitoring models with only a few lots of data can lead to optimistic and erroneous conclusions about model performance and robustness.

This study showed how one can systematically step through options for developing a robust process monitoring model. In this case complexity was added only as deemed necessary. The most robust models tested used a principal components analysis based model combined with an exponentially weighted moving average and covariance.

Remaining issues include the development of rules for resetting a moving mean. This study reset the moving when large shifts occurred as a result of maintenance, cleaning and equipment changes. Methods also need to be developed for selecting optimal weightings for the moving average and covariance. Rules for model updating also need to be developed to avoid updating a moving average and covariance with data from a faulty process.

Glen Ballard

An update has been provided on the project definition and design phases of the Lean Project Delivery System. A primary starting point for the approach is the claim that project teams are responsible for helping customers decide what they want, not just for doing what they are told. Key steps in the process are:

- Clients specify what they are able and willing to spend to get what they want
- How the facility will be used is designed before designing the facility
- Design criteria are developed from values and values from purposes
- Clients engage key members of the project delivery team to help validate and improve project business plans
- Target values and constraints are set as stretch goals to spur innovation
- Design is steered toward targets using a set based approach in which alternatives are evaluated from the outset against all design criteria and constraints and decisions are made at the last responsible moment.

Nelson P. Repenning, John D. Sterman

Process improvements and redesigning efforts have both physical and behavioural dimensions but past scholarly works in this area has focused on one at the expense of other. In contrast, practitioners of TQM and re-engineering offer both technical and organizational tools, but provide no explicit theoretical framework to support their suggestions. The purpose of this paper is to develop grounded theory of improvement and redesign that captures both its physical and organizational dimensions and their interactions. Through the development of explicit feedback models, a representation of both physical and organizational structures of improvement is developed.

Young HoonKwak, Frank T. Anbari

Successful implementation and growing organizational interest in six sigma method have been exploding in the last few years. It is rapidly becoming a major driving force for many technology-driven, project-driven organizations. Factors influencing successful six sigma projects include management involvement and organizational commitment, project management and control skills, cultural change, and continuous training. Understanding the key features, obstacles, and shortcomings of six sigma provides opportunities to practitioners for better implement six sigma projects. It allows them to better support their organizations' strategic direction, and increasing needs for coaching, mentoring, and training.

The statistical aspects of six sigma must complement business perspectives and challenges to the organization to implement six sigma projects successfully. Various approaches to six sigma have been applied to increase the overall performance of different business sectors. However, integrating the data-driven, structured six sigma processes into organizations still has room for improvement. Cultural changes require time and commitment before they are strongly implanted into the organization. Effective six sigma principles and practices are more likely to succeed by refining the organizational culture continuously.

Edward D. Arnheiter and John Maleyeff

A LSS organization would include the following three primary tenets of Six Sigma:

- It would stress data-driven methodologies in all decision making, so that changes are based on scientific rather than ad hoc studies.
- It would promote methodologies that strive to minimize variation of quality characteristics.
- It would design and implement a company-wide and highly structured education and training regimen.

Roger G. Schroeder, Kevin Linderman, Charles Liedtke, Adrian S. Choo
We have proposed an emergent base definition of Six Sigma and an initial theory based on a grounded theory approach. Although Six Sigma builds off prior quality management practices and principles, it offers a new structure for improvement. The structural differences simultaneously promote both more control and exploration in improvement efforts. Some organizations may find benefit from the Six Sigma approach because it fits their organizational needs better. Academics need to better understand Six Sigma so that they do not overhype it or too quickly dismiss it as nothing new. By better defining and adequately understanding Six Sigma, scholars can develop a deeper and richer knowledge of this phenomenon.

Benn Lawson, Danny Samson
This paper proposed the construct of innovation capability to describe the ability of high-performing innovators to achieve effective performance. The notion of capability is useful to apply to innovation as it is the capability to innovate that creates the potential for firm-wide behaviors leading to systematic innovation activities within the firm. We have determined from the literature that innovation capability can be considered to have some seven aspects, namely vision and strategy, harnessing the competence base, organizational intelligence, creativity and idea management, organizational structure and systems, culture and climate, and the management of technology. It is proposed that organizations that consciously and explicitly develop and invest in these aspects of innovation capability, individually and collectively, have a higher likelihood of achieving sustainable innovation outcomes as the engine of their business performance.

Jaap van den Heuvel, Ronald J.M.M. Does, John P.S. Verver
The Red Cross Hospital has successfully implemented Six Sigma and has integrated it within the ISO 9001:2000 quality management system. In doing so, we have produced€1.2 million in annual savings. In training employees and having them initiate Six Sigma projects, we have reduced costs and have improved the quality of healthcare. The results are comparable with those in industry and other hospitals. Since the Six Sigma organization in our hospital is still expanding, we expect to achieve greater substantial savings in the near future. The fact that Six Sigma successfully combines quality improvement and cost reduction substantiates that it could be a solution to present day financial problems in healthcare.

Peter B. Southard, Charu Chandra, Sameer Kumar

Many stakeholders in the hospital environment will be impacted including patients, physicians, nurses, technicians, administrators and other hospital personnel. Different levels of training of hospital personnel will be required, based on the degree of interaction with the RFID system.
Computations of costs and savings will help decision makers understand the benefits and implications of the technology in the hospital environment.

Dr. D. Dixon, Dr. J. Eatock, Prof. B.J. Meenan, and M. Morgan

Validation is a regulatory requirement in both FDA and European medical device regulations. Statistical techniques such as DOE and SPC, which are taught in six-sigma training, can be usefully applied to process regulation. The use of DOE methods, in particular, ensures that the necessary trials are conducted in the most resource efficient manner possible. It is, however, vital that staff have sufficient understanding of the assumptions and modeling methods used in DOE. This knowledge could, for example, be gained by attending a short course and working through several practical examples.
DOE methods allow a large number of variables to be investigated in a compact trial, enable outliers in the data to be identified, and provide detailed process knowledge. The two case studies presented here show that there are indeed tangible benefits to be gained from such approaches. These benefits can result in better production control, i.e.: an increase in product yield whilst at the same time contributing to regulatory compliance.

Output of Literature review

- SPC ensures that processes are fit for industry company specification while reduce the process variation and important in achieving product quality characteristic.
- Its indices are to measure the inherent variability of a process and thus to reflect its performance.
- Process capability indices have been used in the manufacturing industry to provide quantitative measures on process potential and performance.

- The output of a process can be product characteristic or process output parameter. Process capability indices (Cp, Cpk,) provide a common metric to evaluate and predict the performance of processes.
- Capability analysis can be applied not only to production period but also to a machine or machine tool. Capability analysis gives the information about changes and tendencies of the system during production.

- SPC method is more effective for determining the quality problems and solving them in small and medium sized companies that manufacture parts by machining and develop more efficient processes in order to survive in the competitive market.
- It is acknowledged that the benefits of statistical process control (SPC) can be accrued not only in the manufacturing industry but also services industry.
- Statistical process control (SPC) has been acknowledged to be a valuable technique for understanding process behaviour and the making of real-time decisions by operators and managers working in production to bring the process in the state of statistical control by reducing its variability.
- The importance of SPC can be also be depicted through its role as an important component within other continuous improvement (CI) initiatives suchas total quality management (TQM)
- It is necessary to carry out SPC readiness level of an organization before SPC deployment so as to ensure that maximum benefit is achieved.
- Statistical Process Control (SPC) can be expanded to the industrial processing industry and has an obvious significant share in quality aspects of manufacturing industry especially the Medical Industry.
- Process Capability Analysis (PCA) is a Six Sigma analysis phase method, performed to ensure that the process outcomes are capable of meeting certain requirements.
- Continuous improvement of healthcare systems requires the measuring and understanding of process variation. It is important to eliminate extraneous process variation wherever possible, while moving well-defined metrics toward their target values.
- The continuous improvement on quality of products and processes is a constant concern at organizations, as a response to growing competition and demands of the market. The implementation of statistical techniques adjusted to different situations is one way to achieve this goal.
- The development of a statistical control methodology appropriated to the existence of significant process autocorrelation, reveals a crucial importance, since it avoids possible analysis errors.

4. Conclusions

- SPC ensures that processes are fit for industry company specification while reduce the process variation and important in achieving product quality characteristic.
- SPC analysis can be applied not only to production period but also to a machine or machine tool. Capability analysis gives the information about changes and tendencies of the system during production.
- SPC method is more effective for determining the quality problems and solving them in small and medium sized companies that manufacture parts by machining and develop more efficient processes in order to survive in the competitive market.
- Statistical process control (SPC) has been acknowledged to be a valuable technique for understanding process behaviour and the making of real-time decisions by operators and managers working in production to bring the process in the state of statistical control by reducing its variability.
- The importance of SPC can be also be depicted through its role as an important component within other continuous improvement (CI) initiatives such as total quality management (TQM)
- It is necessary to carry out SPC readiness level of an organization before SPC deployment so as to ensure that maximum benefit is achieved.
- Statistical Process Control (SPC) can be expanded to the industrial processing industry and has an obvious significant share in quality aspects of manufacturing industry especially the Medical Industry.

References

1. “Process Capability Studies” prepared by M. Suozzi, Member of the Technical Staff, Hughes Aircraft Company, Tucson, Arizona, 27NOV90] .
2. Performance Test Methodology for 3-Axis Machining Centre Habibah Binti Jamaludin Faculty of Manufacturing Engineering June 2006.
3. Analysis of Vertical Machining Centre Components by 1) Anayet U. Patwari 2) Waleed F. Faris 3) A. K. M. Nurul Amin and 4) S. K. Loh on 13 October 2009.
4. Manufacturing Process Capability and Specification Limits
5. Matti Mottonen*, Pekka Belt, Janne Harkonen, Harri Haapasalo and Pekka Kess
6. Department of Industrial Engineering and Management, University of Oulu, Finland
7. Static and dynamic performance of High Speed Vertical Machining centre spindle box by Rongchang Li, Aixia He.

8. Jabnoun N (2002). Control processes for total quality management and quality assurance. Work Study; Vol.51, No.4, pp.182–90.
9. Xie M, Goh TN (1999). Statistical techniques for quality. TQM Mag; Vol.11, No.4:238–42.
10. Chaudhry SS, Higbie JR (1989). Practical implementation of statistical process control in a chemicals industry. Int J QualReliab Manage; Vol.6, No.5.
11. Pearn WL, Chen KS (2002). One-sides capability indices Cpu and CpL: decision making with sample information. Int J Quality Reliab Manage; Vol.19, No.3:221–45.
12. Xie M, Lu XS, Goh TN, Chen LY (1999). A quality monitoring and decision-making scheme for automated production process. Int J Quality Reliab Manage; Vol.16 No.2:148–57.
13. Ercan F (1987). Quality control on the industrial area, Ankara: Gazi University, p. 66–100.
14. Ali RızaMotorcu, AbdulkadirGu¨ llu¨ (2006), Statistical process control in machining, a case study for machine tool capability and process capability, Materials and Design Vol.27, 364–372.
15. M. Elg, J. Olsson, and J. J. Dahlgaard,"Implementing statistical process control: an organizational perspective," International Journal of Quality & Reliability Management, vol. 25, pp. 545-560, 2008.
16. “Process Capability Studies” prepared by M. Suozzi, Member of the Technical Staff, Hughes Aircraft Company, Tucson, Arizona, 27NOV90] .
17. Performance Test Methodology for 3-Axis Machining Centre Habibah Binti Jamaludin Faculty of Manufacturing Engineering June 2006.
18. Analysis of Vertical Machining Centre Components by 1) Anayet U. Patwari 2) Waleed F. Faris 3) A. K. M. Nurul Amin and 4) S. K. Loh on 13 October 2009.
19. Manufacturing Process Capability and Specification Limits
20. Matti Mottonen*, Pekka Belt, Janne Harkonen, Harri Haapasalo and Pekka Kess
21. Department of Industrial Engineering and Management, University of Oulu, Finland
22. Static and dynamic performance of High Speed Vertical Machining centre spindle box by Rongchang Li, Aixia He.
23. Jabnoun N (2002). Control processes for total quality management and quality assurance. Work Study; Vol.51, No.4, pp.182–90.
24. Xie M, Goh TN (1999). Statistical techniques for quality. TQM Mag; Vol.11, No.4:238–42.
25. Chaudhry SS, Higbie JR (1989). Practical implementation of statistical process control in a chemicals industry. Int J QualReliab Manage; Vol.6, No.5.
26. Pearn WL, Chen KS (2002). One-sides capability indices Cpu and CpL: decision making with sample information. Int J Quality Reliab Manage; Vol.19, No.3:221–45.

27. Xie M, Lu XS, Goh TN, Chen LY (1999). A quality monitoring and decision-making scheme for automated production process. Int J Quality Reliab Manage; Vol.16 No.2:148–57.
28. Ercan F (1987). Quality control on the industrial area, Ankara: Gazi University, p. 66–100.
29. Ali RızaMotorcu, AbdulkadirGu¨ llu¨ (2006), Statistical process control in machining, a case study for machine tool capability and process capability, Materials and Design Vol.27, 364–372.
30. M. Elg, J. Olsson, and J. J. Dahlgaard,"Implementing statistical process control: an organizational perspective," International Journal of Quality & Reliability Management, vol. 25, pp. 545-560, 2008.