

ANALYSIS OF THE BENEFITS OF USING DESIGN OF EXPERIMENTS IN VALIDATION OF A NEW METHOD/PRODUCT

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—Abstract—

Total Quality Management as a holistic management system is widely practical in every organization these days and one of the foundations of TQM which should be taken into account in all functions of the company is continuous improvement.

In order to improve the quality and establish the qualification of a new product/method – based on recent and future customer needs-, validation is a useful process during the development and before launching that product/method. The variability is also important to be reduced for quality improvement.

Statistical methods are the most capable techniques for the purpose of validation and reducing variability in any organization.

Design of Experiments is one of the statistical methods in which the important sources of variability are identified besides it helps to establish decisions on facts and execute quality improvements by systematic data gathering.

Key Words: *Quality Management; Continues improvement; Statistical method; Design of experiments; Validation; Experimental*

JEL Classification: C90

1. INTRODUCTION

In this highly competitive world nowadays, loyal customers play important roles in survival of any organization. According to Bergman and Klefsjö (2003), to have this kind of faithful customers and keep them satisfied, companies have to discover their needs and expectations – present and future- and fulfill them. “*The quality of a product is its ability to satisfy or preferably exceed, the needs and expectations of the customers*” (Bergman & Klefsjö, 2003: 24).

Therefore it is vital to focus on quality of the product and its improvement to win in this competitive market.

To improve the quality, the variability is important to be reduced and statistical methods are the most capable techniques for any organization in this field. On the other hand statistical techniques are useful in validation of the product which helps to improve the quality (Montgomery, 2005).

After generating a product with required specifications, a method which has the ability to validate whether these requirements have been met or not could be helpful. “*Validation is defined as the confirmation by examination and provision of objective evidence that the particular requirements for a specified intended use are fulfilled*” (ISO 1994b cited in Richard Boque, 2002: 129).

One of the most useful tools for validation is Design of Experiments (DOE) in which a collection of factors that may have any effect on the product is considered and the important sources of variability are identified (Dr. Dixon, et al., 2006). Hence, DOE helps to establish decisions on facts and execute quality improvements by systematic data gathering (Bergman & Klefsjö, 2003).

Design of Experiments is a statistical method which applies to a series of tests to analyze the response against the changes in levels of input variables. So in this method, it is essential to identify all the probable input variables and output of the process as the response which its improvement is the main goal (Barrentine, 1999).

There are several steps to implement Design of Experiments; briefly, defining the process for the specific problem is the first step. The next step is to determine the response, the factors and their levels. Then, choose the experimental design and

perform it. After that, data analysis, finally conclusion and recommendation would be defined which leads to determine our validation result.

In addition, Design of Experiments has some advantages like (Dr. Dixon, et al., 2006):

- The critical factors besides the best condition in which there is minimum variation, would be identified.
- The number of experiments would be decreased therefore the cost of process validation would be reduced.
- The effect of interaction between factors would be evaluated.

In this paper we are going to express the benefits of DOE in validation with the aim of publishing and using a new method/ product.

2. Method

2.1. Validation

Definition of Validation depends on which context the company is working in. But in general it is the process in which a product or a method is guaranteed to meet defined customer needs and requirements under specific operating condition. Validation has many applications in quality testing and quality assurance. Besides it gives better knowledge to improve manufacturing processes.

There are some useful tools to validate a process such as SPC, DOE, FMEA and etc which will be described briefly below.

It is worth to mention that, statistical methods are the most useful amongst the others in validation and they are completely practical in many different areas like computer science, food industries, medical science, different laboratories, and etc (Dr. Dixon, et al., 2006).

2.2. SPC

Generally, Statistical Process Control (SPC) is based on the collected natural data and has the ability to find out whether a process is in between the particular limitations. So it is a useful tool for validation in which every process will be studied whether it will stay within these limitations. Therefore it is necessary to define specific criteria and its limitations for any process in order to provide information to do the evaluation by SPC (Srikaeo & Hourigan, 2002).

Also SPC could possibly identify changes and real errors to the process which can arise from serious mistakes and determine whether any improvement would be needed (Küppers, 1997).

2.3. FMEA

Failure Mode and Effects Analysis “ is a specific methodology to evaluate a system, design, process, or service for possible ways in which failures (problems, errors, risks, concerns) can occur” (Dale & Shaw, 1990 cited in Şansli Şenol, 2007: 31).

Since Validation is the confirmation by examination, and any examination carries some degree of risks which could arise from different failures and some of these failures can never be totally eliminated, so they can be determined by FMEA which is a kind of problem analysis tool.

This tool has the ability to discover any failures even a simple one and then categorizes the causes and consequences of the failures and determine the probability of occurring these failures in order to simplify the decision making in validation process (Dyadem Press, 2003).

2.4. Design Of Experiments

To base decision making on facts is an important cornerstone of TQM. Collecting data in a systematic way is necessary to make factual decisions and improve quality. To achieve this, it is better to use statistical methods which are practical among other methods. Since the natural data during the product and process operation are not always enough, generating more data by design of some desired experiments could provide more knowledge to produce best products through a low cost process. Thus Design of Experiments is the proper tool which gives the opportunity to observe and analyze the effects of some intended changes that are made to a series of tests to identify the best results of the process.

DOE has different types as following:

- single factor
- Full factorial designs
- Fractional factorial designs
- Taguchi methods
- response surface(curve) models
- mixture methods

Each type has specific usage. For instance, when the sources of variability or the critical factors for further development is needed to be considered, it is better to use the two level trials (in full or fractional factorial designs), while in robust design process it is often recommended to use Taguchi methods which locate the operating conditions in order to minimize the product variation.

The sequence of implementing DOE starts with an important step which is identification of all aspects and gaining complete knowledge about the problem and the objectives. Since a clear identification in this step leads to a better interpretation of the problem and gives better solutions, all of the ideas from different concerned parties have to be considered. The next step is the determination of input variables (factors) and output (response). After selecting effective factors, their ranges of variability which their efficiencies are desired to be measured should also be defined as levels. Designing the experiments is the next step in which the sample size and the suitable type of DOE for the specific purpose are selected. In the performance step, since any error during the execution might destructively change the results, the process has to be followed up in order to check if it is being performed according to the plan. To prevent tendency of the result, it is crucial that the tests will be done randomly.

The next step is analysis of effects which is divided into the following phases (Barrentine, 1999):

- Calculating the effect of each factor and their interactions.
- Making a Pareto chart in order to illustrate the value of each effect.
- Performing the Analysis of Variances.
- Determining and graphing the significant effects.
- Determining the regression model.

The achieved results from the analysis would be reliable if the experiments previously had well designed and right performed steps.

The final step is conclusion of the results and recommendations. To make the conclusions more tangible, it is better to utilize the appropriate graphs and diagrams (Montgomery, 2005).

The achieved results would present whether the new method/product is validated or not. Besides it could determine the best condition in which the intended results could be achieved.

Also some actions might be recommended for further developments.

2.5. Why to choose DOE?

There are different reasons to choose Design of Experiment in many projects. Some of them are listed below:

- DOE creates the opportunity to estimate the best condition proportional to the target.
- In comparison to SPC and FMEA, Design Of experiments is more efficient since it helps to make the number of experiments appropriate so that it leads to use the resources like money, time and machine in an efficient way.
- DOE is fluctuated in the size of experiments because it varies according to the objective and its different models. And it has the ability to optimize sample size on the contrary SPC requires a large sample.
- It is possible to consider the effect of all factors separately as well as the interactions between them in DOE while FMEA cannot survey more than one failure each time (Dyadem Press, 2003).
- DOE gives the opportunity to observe and analyze the effects of some intended changes that are made to a series of tests to identify the best results of the process.
- Since the natural data during the product and process operations are not always enough, generating more data in DOE by design of some desired experiments could provide more knowledge to produce best products through a low cost process. While FMEA and SPC do not have such ability.
- It is a basic technique for well-known methodologies like six sigma
- DOE has different types. Each of them has specific usage which provides us a wide range of applications.

3. CONCLUSION

Generally, in the development of any new method/product, validation is necessary to be performed to demonstrate the qualification and competency of the method.

In this paper, the different tools for validation of a new method/product have been expressed which in between the Design Of Experiments (DOE) indicates more

benefits of being able to prove that the desired results were achieved and besides, to determine the condition which led to the best result.

Since in a method/product, a particular result usually comes from a particular condition (type of material, range of operation and etc), so the validation should consider the whole condition in order to be applied to the method/product (Taverniers et al., 2004) ; and it would continue to emphasize on excellence of Design Of Experiments.

In fact, validation is a process which investigates whether the results from the method conform to the intended results under the certain conditions. It is worth mentioning that the desired results-the validation pattern- are defined according to customer needs and expectations in order to improve their satisfaction so that it leads to increase loyal customers. Additionally, through a validation process by DOE, it will be discerned if any changes in the method are necessary. If so, after the changes were made, it is important to do the revalidation.

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