INSIGHTS

Variation Research: Powerful Techniques for Improving Manufacturing Process Quality

By Jim Dougherty

Executive Summary

Variation research is a highly effective set of techniques that can result in profound improvements to manufacturing processes. The reduction of waste, rework, rejects, and external failures result in cost-savings, which contribute directly to the firm's bottom-line. Additionally, there is the benefit of increased manufacturing capacity, achieved by turning the time spent producing nonconforming product into time spent producing acceptable product.

Considering the level of economic loss due to quality problems associated with most manufacturing processes, it is logical to question why nearly every production process in almost every manufacturing facility has not undergone some sort of systematic variation research effort. The reasons include, but are not limited to the following:

- Although reasonably well known within certain technical disciplines, these techniques are far from universally understood and appreciated.
- More than an academic understanding of these principles is required for their effective use. Just as studying music theory alone will not produce a skilled musician, a theoretical understanding of the techniques alone will not yield a skilled practitioner. Most manufacturing facilities do not have someone with the required skills on-site.
- Many manufacturing facilities are staffed in a manner where day-to-day operations require nearly all of the available human resources. A variation research project, for example, typically involves assistance from several functional groups; without strong management commitment, the required resources are not likely to be made available.

Given the increasing global competition in the manufacturing arena, perhaps the question that manufacturers should ask themselves is not whether they can afford to invest in variation research initiatives, but whether they can afford not to.

Background

It has been decades since quality guru Joseph Juran first posed the concept of the Hidden Factory, but it remains a useful introduction for variation research. Essentially, the idea is that if all of the resources within a given manufacturing operation that are associated with the production of nonconforming product were quanti-

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fied (including people, machinery, floorspace, utilities etc), the size and resource requirements of the facility needed to produce this waste would be surprisingly large. The Hidden Factory potential is the extra positive output that would occur if the resources used to produce waste were redirected to produce acceptable product. It has been estimated that the costs associated with the Hidden Factory typically comprise between 15% and 40% of total manufacturing resources. There are many ways to address the Hidden Factory problem; this paper presents an overview of variation research, which perhaps has the greatest potential to increase manufacturing efficiencies and reduce costs.

Discussion

Manufacturing-related quality issues are the result of variation in the manufacturing process. If any manufacturing process had absolutely no variation of any sort, then every item produced would be perfect (assuming proper design). If this were the universal case, there would be no need for any manufacturing-related regulatory requirements or quality assurance systems; everything would always be perfect. Costs associated with waste, rework, rejected product, field failures, etc. would be nonexistent. This level of performance represents an ideal, and probably unattainable level for any manufacturing process. However, there is nearly always a significant gap between how well a manufacturing process actually performs, and how well it is capable of performing (using existing equipment materials, components, etc.). How to narrow that gap (i.e., reduce variation) and thereby solve the quality problems is a tactical issue that can be well served by the application of techniques collectively known as variation research.

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In addition to incorporating common statistical problem-solving techniques, variation research also integrates other unique methods, and is structured in a sequence that makes the overall process extremely efficient. Variation research focuses on improving product quality by identifying the main causes of variation. Once identified, the removal of these causes is usually relatively easy. The sources of variation for virtually all manufacturing processes contribute very unequally. Typically, controlling the most significant cause (often referred to as the "Red X") has a disproportionate effect on the reduction of total variation.

Variation research techniques are not new. Dorian Shainin first combined multi-vari analysis (which was developed by Leonard Seder in 1949) with experimental design in the early 1950s. He revolutionized quality problem solving during the following four decades. (One of his protégés, Tom Woods, was my coach and mentor for the application of these techniques.)

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It should be noted that, although variation research focuses primarily on improving existing manufacturing processes, it can also be beneficially applied to new processes. For example, it can be used to ensure compliance with FDA's process validation requirements for a medical device manufacturer. The data generated can be used to document that important process parameters have been optimized and controlled.

In most instances, manufacturers have sound data regarding the sources of their economic losses on the manufacturing floor. However, it is the identification of the causes of these chronic sources of loss that poses the real challenge. For example, a manufacturing supervisor once claimed to me, "I have been running this line for 15 years and I can tell you what the biggest problem is and always has been. We throw away more work for not meeting the assembly concentricity specification than for all other reasons combined. The problem is that there is nothing I can do about it. It is inherent in the process that some of the product won't meet the specification, and it is killing my efficiency." This example will be followed through each sequential step of the variation research process.

Six-Step Variation Research Process

Variation research can be viewed as a six-step process. In chronological order, the steps are: Prioritize, Quantify, Eliminate, Experiment, Optimize, and Control.

STEP ONE: Prioritize

This step is somewhat self-evident. Processes selected to undergo a variation research initiative should have potential for significant gain. Typically, the main benefit is cost-savings, which is derived from a reduction in failure costs, both internal and external. However, processes that may produce a rare, but potentially severe defect, such as a catastrophic field failure of a medical device, are also viable candidates for variation research.

The six steps of variation research are Prioritize, Quantify, Eliminate, Experiment, Optimize, and Control.

In the example, the supervisor analyzed the waste, and learned that 56% of the waste from his line was due to product not meeting the concentricity specification; this waste corresponded to an annual loss of $176,000. Additionally, customer complaints (associated with units of product having this defect that were not detected and removed during the manufacturing process) were not quantified, and are thus not included in the $176,000 loss.

STEP TWO: Quantify

A key premise of variation research is that the information needed to solve the problem is hidden somewhere in the process, and to penetrate the problem, we

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need to "let the process do the talking." One element of "listening" to the process is measuring the offending variation; often the mechanism for doing so is already in place. Quality requirements that are assessed by an analytical balance, micrometer, chemical assay, or tensile test instrument already have a variable scale of measurement in place to quantify the characteristic of interest. In the example, a template was used to determine whether a given sample met the specification. This device did not actually measure the characteristic; it only determined whether a sample was within the specification limit (acceptable), or whether it was rejectable. For variation research purposes, it was necessary to measure the amount by which a given sample was non-concentric. The manufacturing supervisor would say, "This part fails." The experimenter would say, "This part is off-center by 0.193 inches."

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It is important to note that for variation research purposes, specification limits are not relevant. The process itself, and how it behaves, is the focus of the study. Specification limits do not affect process variation, and therefore are of no value when studying it.

STEP THREE: Eliminate

More than any other step, elimination differentiates variation research from other approaches to statistical problem solving, and is responsible for much of its efficiency. It is essentially a process of elimination, and is analogous to the powerful, but simple technique that can be used to identify a specific word someone has mentally selected from a large unabridged dictionary by posing no more than 17 yes/no questions. If you open the dictionary to its midpoint, point to the bottom word on the left page, and ask whether the secret word is before the selected word, the answer will allow you to eliminate half of the words in the dictionary. Continue to subdivide the dictionary using this technique, and you can narrow the choices down to the secret word with 17 or fewer questions.

The process of elimination is the foundation for the multivari study. This technique is an analytical/graphical tool that charts the data in a manner that isolates the effects of different groups of causes: "within-the-piece," "piece-to-piece," and "time-to-time." The result of this analysis is that a large proportion of potential causes can be eliminated from consideration. The essence of the multivari study is that it does not identify what is the Red X, but it provides much information regarding what is NOT the Red X, thus allowing those variables to be eliminated from the next step.

Often, there are several ways in which to structure a multivari analysis, however, most of these options would fail to provide the most beneficial information. A

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degree of experience and ingenuity is required to construct the study so that maximum benefit is obtained.

In the example, the greatest amount of concentricity variation was found to be piece-to-piece. Factors that would cause excessive variation to occur over relatively long time intervals (time-to-time), such as material and component lot, and machine setup, were eliminated from consideration as experimental variables. The same was true for those factors that would cause within-the-piece variation.

STEP FOUR: Experiment

Experimentation is where variation research is similar to many conventional statistical problem-solving approaches, and is where the elusive Red X is identified. The key difference is that the field of potential causes has now been reduced significantly. Therefore, there are far fewer experimental factors to be considered, thus greatly reducing the time and expense required for this stage.

Techniques employed in this phase naturally vary depending on the specific circumstance. The experimental design is selected based on the number of factors to be evaluated, the number of levels of each factor to be evaluated, and the importance of identifying interactions. Full factorial designs, which evaluate all levels of all factors, provide the most information, but are only practical when evaluating a few factors. Fractional factorial designs (including Taguchi, Box-Behnken, and Plackett-Burman) are useful for screening the effects of many factors, and are useful for further reducing the number of factors under consideration. Variation research also includes nontraditional experimental techniques such as variables and components search. Standard statistical techniques such as Analysis of Variance (ANOVA), as well as simple and multiple regression, are used to evaluate the experimental results.

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In the example, nine factors were identified as experimental factors; had the multivari study not been performed, the number would have been several dozen. A quick and inexpensive fractional factorial experiment yielded the information that the Red X was one of four factors, or an interaction among them. A subsequent full factorial experiment focusing on the four remaining factors identified the Red X. When a component that was within specification for its diameter, but near the lower specification limit, happened by chance to be placed in a fixture (there were 24 on this particular line) that had a centering pin orifice that was within specification but on the high side (due to wear), a defective part was often the result. This combination of factors (small diameter component and large pin orifice) working together to cause the offending variation in the product is known as an interaction.

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Interactions cannot be detected by the all too common, but highly inefficient experimental technique of changing only one thing at a time. Had this technique been employed for our example, the Red X would not have been uncovered.

STEP FIVE: Optimize

When the process variable responsible for the offending variation (the Red X) has been identified, the next step is to manage it. Further experimentation focused on determining the optimum value or range for the variable may be warranted. In some circumstances, iterative techniques such as evolutionary optimization (EVOP), which can be performed in conjunction with routine production, are the appropriate choice.

In many instances, no further experimentation is necessary, as was the case in the example. The source of the $176,000 annual loss was eliminated by introducing a preventative maintenance procedure, whereby very inexpensive bushings were replaced annually, as opposed to only when they cracked. This step also had an additional benefit of reducing the unplanned downtime that occurred when the line had to be stopped, and a cracked bushing replaced. The output of the line per shift increased because fewer units were discarded. Customer complaints and the corresponding costs associated with the concentricity problem vanished.

STEP SIX: Control (If Necessary)

The final step in the process is to determine if it is appropriate to introduce process control. Statistical process control (SPC) techniques are sometimes appropriate. There are a variety of techniques, and, as with the experimental design, the most strategic technique depends on the specific circumstance. The decision regarding whether to introduce a control system should be based on cost and benefit. The purpose of these techniques is to provide advance notice that unless action is taken, defective material will be produced. In the example, the decision was to not utilize SPC because it was much more economical and just as effective to replace the bushings annually than to periodically measure the diameters, chart the results, and replace the bushings when the diameters approached the dangerously large size.

Investing in variation research is imperative for the long-term manufacturing viability and profitability of an organization.

Conclusion

The six steps of variation research: Prioritize, Quantify, Eliminate, Experiment, Optimize, and Control have been used by numerous companies to achieve dramatic improvements in manufacturing process quality and corresponding cost-savings. Historically, the impetus for variation research initiatives has been the desire to improve profit and competitive position. Given the global competitive

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manufacturing pressure that now exists, the scope of the impetus for these initiatives may well now include the very survival of these manufacturing facilities.

Investing in variation research is imperative for the long-term manufacturing viability and profitability of an organization. Rework, waste, and product that does not conform to specifications will not only hurt a company's bottom-line, but may yield potentially detrimental consequences, such as legal actions and government intervention, from which a company may never fully recover. Variation research can yield long-term dividends by allowing you to identify problems early on, thus improving manufacturing efficiencies and reducing risk. Are you willing to risk the future of your company?

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