

CASE STUDY

Six Sigma Quality Improvement at BD Company



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by

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I. INTRODUCTION

There have been numerous quality initiatives over the last 25 years starting from Quality Circles, SPC, TQM, ISO, and Malcolm Baldrige National Quality Award (MBNQA). A few of the reengineering concepts, such as Kaizen, Kanban, and Lean manufacturing were also applied along with the above initiatives. Manufacturing companies, which implemented the above initiatives reaped financial benefits by lowering the cost of poor quality (COPQ), which includes reducing cycle time, and reducing customer complaints. The lessons learned from these quality initiatives have culminated in the Six Sigma methodology for breakthrough process improvement. The Six Sigma methodology not only improves quality, but also focuses upon cost of goods sold and return on investment. Competitive pressure, customer demand for defect free products and services at low prices and higher expectations of stakeholders, require breakthrough approach in everything done in business.

Motorola developed and implemented Six Sigma quality methodology and successfully bid for MBNQA in 1988. The strategy and technical details are given in the Technical Report by Harry (1). Later, IBM (Rochester, MN) and Texas Instruments (DS&E) emulated Motorola's Six Sigma quality methodology and won MBNQA in 1990 and 1992, respectively. Allied Signal and more recently, GE jumped on the bandwagon and successfully strategized the implementation of a Six Sigma quality program as business initiative as reported by Hoerl (2). Jack Welch, CEO of GE, requires career advancement for all GE employees through the successful experience in Six Sigma initiatives. As a result of this requirement, thousands at GE took Six Sigma training and implemented it in their projects. Six Sigma methodology is a way of business for both technical and non technical departments, at GE.

Ed Ludwig, President of BD, is the sponsor of BD's Six Sigma initiative. He believes that this initiative represents 'business transformation' in its truest sense and further, it demonstrates BD core values in action while achieving improved performance, organizational development, and relevance to healthcare throughout the world.

II. WHAT IS SIX SIGMA?

1) Six Sigma is a philosophy of total customer satisfaction. Customers are satisfied if the product is defect free (including latent defects), delivered on time at low prices. In addition to that, the ever changing customer requirements and expectations, and competitive prices put pressure on manufacturers to distribute better and cheaper products. Six Sigma is that philosophy of breakthrough quality improvement by reducing variation, defects, and by increasing robustness of product and processes. Implementation of Six Sigma is a key strategic quality goal, which should be a part of a company's business plan.

2) Six Sigma is metrics. For variables response, potential process capability index, C_p and actual process capability, C_{pk} must be 2.0 and 1.5, respectively with a defect rate no more than 3.4 ppm. Figure 1 show explanation of short-term Six Sigma process for a single vital product characteristic, when the process is centered. Figure 2 depicts the same process, but perturbed over a long-term due to variability in the process such as tool wear, machine set up, new batches of materials etc. This shift, which degrades the process average, is approximated 1.5 sigma

For count data, defects per unit (DPU) are converted into defects per million opportunities (DPMO). DPMO is transformed into Z value, which is also called Sigma capability. The above metrics is universal in nature that can be used for benchmarking across industries, plants, processes, products, and services (3).

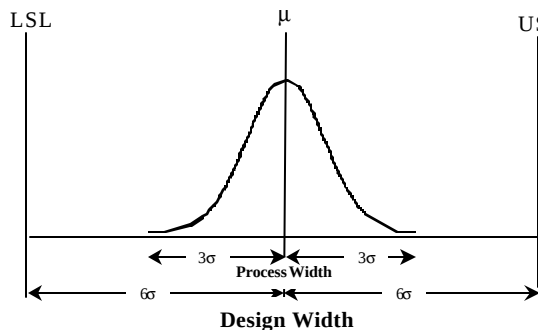


Fig. 1: Short term - Centered process

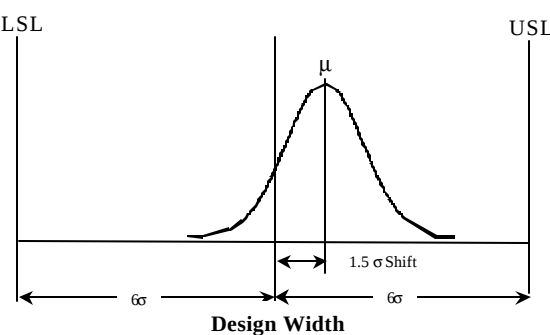


Fig. 2: Long term - Shifted process

3) Six Sigma as process consists of five steps to achieve Breakthrough Improvement:

- A. Define the issue, product characteristics that affect customer satisfaction
- B. Measure the response factors (outputs/Ys) and baseline metrics
- C. Analyze the process parameters (inputs/Xs) that affect response factors
- D. Improve the process response factors by design of experiments (Understand the nature of the function, f in $Y = f(X)$)
- E. Control the gains, robustness of the process response factors

4) Six Sigma is a quality goal, with defects approaching zero or no more than 3.4 ppm defective. The Sigma capability and the corresponding defect level are given in Table 1

± Sigma Capability	Centered Process (ppm defective)	± 1.5 s Shifted Process (ppm defective)
3 Sigma	2,700	66,800
4 Sigma	64	6,200
5 Sigma	0.6	230
6 Sigma	0.002	4

Table I: Sigma Capability Vs. ppm Defective

Most of the manufacturing processes in the USA are between 3 and 4 Sigma level. A tenfold increase in quality (i.e., 1/10 decrease in defects) per year is a realistic goal. A company may take five years to achieve Six Sigma capabilities for its key processes.

5) Six Sigma uses a set of quality and statistical tools for data gathering and analysis of information. Besides the 'Magnificent Seven' statistical tools, several other advanced tools such as test of hypotheses, regression analysis, design of experiments, and failure mode and effect analysis (FMEA) are used. It is interesting to note that there are no new tools in Six Sigma methodology that have not been used in TQM, except that Six Sigma uses a structure that prescribes the exact order when these techniques and tools should be used. For example, problem definition is done first; measurement system analysis is done next; later vital few independent variables are identified from the useful many by means of process mapping, Cause & Effect diagram, Product/process design matrix (PDM), and FMEA before the Improve Phase. Similarly, robust process/product design, which requires statistical design of experiments, is done only after calculating gage reproducibility and repeatability (GR&R) of response, and after identifying the key input variables.

What is needed in Six Sigma is statistical thinking about a problem rather than statistical expertise for analysis and interpretation. Modern computer technology has reduced the complex calculations to a few finger strokes, which produce color graphs, tables, and host of much useful information.

III. SIX SIGMA METHODOLOGY FOR CUSTOMER SATISFACTION

Six Sigma is a breakthrough methodology rather than continuous improvement. It is certainly customer driven. A customer is satisfied if the product is defect-free, delivered on time as promised, does not fail early in life, and does not fail excessively in service; and it is offered at economic prices. That is to say, a customer demands the best quality at the best prices. In many companies, this is not feasible because most manufacturing processes are not robust and waste too much time and resources in inspection, testing, reworking, and scrapping. Six Sigma initiatives offer a structured methodology of breakthrough improvement to assure total customer satisfaction, not just manufacturing but also other functions of business enterprises. The ultimate goal of quality improvement is

zero defects in all key processes/products at BD. What is the Sigma capability of a plant, a department, a process, or a product? Many business leaders and functional heads do not know the quality level/Sigma capability of their products and services. The goal of continuous quality improvement is to reach Six Sigma capabilities.

Mathematical Model of Defect Distribution: Product variability and product out of specifications are the primary causes of customer dissatisfaction. A defect is anything that results in customer dissatisfaction or not meeting customer expectations. Larger the product variability and defects in a product, lower the customer satisfaction will be. If one hundred parts are inspected and one defective part is found, then we have 0.01 fraction defective or 10,000 ppm defective (1 defective part/100 parts).

In many companies, the key processes are at 3 to 4 Cpk or higher. They produce far less defects than the above example. If defects are rare and randomly distributed, Poisson distribution model may be used to predict defects. The probability of getting a part with q defects, P(q) is:

$$P(q) = \frac{u^q e^{-u}}{q!} \quad \text{Where } u = \text{Average \# of defects per unit, DPU}$$

q = # Defects on a particular unit

$$P(q) = \frac{DPU^q e^{-DPU}}{q!}$$

For proportion of units containing no defects, i.e. q = 0

$$P(q = 0) = e^{-DPU}$$

First pass yield, FPY = e^{-DPU}

Conversely, if we know yield, an estimation of defects is:

$$DPU = -\ln(\text{FPY})$$

Six Sigma Methodology for Productivity: The effect of Sigma capability on first pass yield (FPY) and Rolled up FPY is dramatically very low with the increase in the manufacturing complexity as explained in Table 2. If a process is operating at three sigma level, it will produce 93.2% FPY. If there are two components or two step process, then the rolled up FPY will be 86.86% (.932 *.932). However, if a process has 10 components, each operating at three sigma capability, the rolled throughput will be 50.09% (.932 **10), a dramatic yield loss. That is why, a manufacturing or assembly process at three or four Sigma level is not competitive. Only a Six Sigma process will guarantee defect-free product with no scrap.

± Sigma Capability	1 Component Process	10 Components Assembly	40 Components Assembly	100 Components Assembly
3 Sigma	93.2%	50.09	6.0	0.10%
4 Sigma	99.379	93.96	77.94	53.64
5 Sigma	99.9767	99.77	99.07	97.70
6 Sigma	99.99966	99.9966	99.98	99.96

Table2: Rolled up Yield (Per Cent) Vs. Multi-component Assembly Process

Table 2 shows that the throughput yield of the three Sigma process is the most inefficient and that of the Six Sigma process is the most robust. Manufacturers operating at 3 or 4 Sigma and having multi-component assembly will extensively test and rework and

are unlikely to deliver on time. On the other hand, a thousand parts assembly at Six Sigma will be robust, yielding 99.66%

IV. SIX SIGMA IMPLEMENTATION STRATEGY

Six Sigma quality model embraces the concept that quality is the responsibility of all, who work in an enterprise not the responsibility of QA personnel only. Quality Assurance department cannot be responsible for the failure mode of new products at R&D, defective parts at Manufacturing, quality of Sales & Distribution services, errors and omissions in the budget making process. At BD, each person and each function is required to take responsibility for his/her own work. However, there are two key individuals in Six Sigma implementation.

Six Sigma Champions or Mentors: Champions are influential management representatives, who provide strategic direction for project selection and support. They act as mentors to their sponsored Six Sigma teams and remove any roadblocks. Champions are responsible for the success of a Six Sigma project and communicate with the site leadership.

Six Sigma Black Belts or Six Sigma Team Leaders: Black Belts are team leaders, who are responsible for implementing the Six Sigma methodology in their projects. They are expected to coordinate team activities and be accountable to their Champions. As shown later, the Black Belt candidates are identified and trained from all functions of a plant, both from technical and non-technical areas. Having taken up an intensive training, the Black Belts are expected to lead 3 to 5 Six Sigma project teams concurrently per year.

BD conducted a pilot Six Sigma training program recently. The Black Belts were given four weeks of classroom training, which focussed upon breakthrough improvement step by step. A multi-national class of 28 Black Belts, representing BD businesses from nine countries was assembled in the first wave of training. Juran Institute was selected as the training partner. This was hands-on training with about one-month of application of the methodology on their project between each of the five phases. Six Sigma Champions also received a two day training. It was about their roles and responsibilities, and an abridged orientation of the Six Sigma methodology.

Six Sigma improvement projects follow a structured five step process. They are define, measure, analyze, improve and control, DMAIC phases.

1. Define Phase: Potential Six Sigma projects are identified and selected based upon customer needs, internal and external audits, and strategic business plans. Nevertheless, customer needs are documented. The project should be relevant, and should impact business measurably by increasing customer satisfaction and by reducing the cost of poor quality (COPQ). Tools used in define phase are process flow mapping, business score card, Pareto analysis and the calculation of COPQ. Select a multi-functional team of 4 to 8 members, who are knowledgeable in the area. Prepare a mission statement, describing the problem and team's objective, which should be specific and measurable. A Six Sigma project should be strategically relevant and impact financial objectives at the conclusion of the project in 4 to 6 months.

2. Measure Phase: The basic purpose is process characterization, i.e., to measure baseline performance and document the process by identifying key product characteristics (Ys) and key process parameters (Xs). Data collection with an appropriate sampling plan and analysis of the data by line graphs, bar graphs, stratification and pareto graphs is done. Select key product responses, and investigate the key variables by Cause and Effect diagram, brainstorming, PDM matrix and FMEA. Measurement system is validated for accuracy, linearity, stability, and resolution. GR&R of the product characteristic is calculated that should be in an acceptable range. Baseline potential process capability, Cp, and actual process capability, Cpk for the key responses (Ys) are also estimated.

3. Analyze Phase: Investigate numerous independent variables (inputs) that may affect response variables (outputs), then narrow the list of vital few inputs from the trivial many:

$$Y = f(X_i)$$

where, the Xs are the inputs, which drive the process output and include materials, measurements, methods, machines, manpower, and mother nature. Y is a dependent response variable, which is a product characteristic, e. g., length of a dimension or wall thickness.

Specific statistical tools are used to identify primarily the key input variables (Xs) and to estimate the corresponding response in this phase.

- Categorical inputs (Effect of different machines, operators, and shifts on a product)
Use Box plots, main effects plots and multi-vari analysis.
- Variable inputs (Effect of temperature, pressure, time, speed)
Use correlation and regression analysis.
- Categorical process outputs (Defects, defective products, any counted response)
Use contingency tables
- Variable process outputs (Strength, outer diameter of a part)
Use correlation and regression analysis

Each of the above statistical analyses is tested for significance at 5% alpha. Significant variables may be the vital few inputs (Xs), non-significant variables are the trivial many, which are eliminated from further considerations.

4. Improve Phase: Thus far, the data was obtained from the current process passively, i.e., without any intervention. A narrow list of key independent variables is obtained from the passive data by applying the quality and statistical tools. Now study the effect of the selected key input variables on the response as identified in Phase2. Statistical design of experiments may be run to study the effects of multiple input factors upon product characteristics. Analysis of variance is a well-established technique for testing the significance of multi-factor inputs on product response.

First, run a 2-level small screening design to determine the key inputs. Having decided upon the most important key input variables, run a higher resolution design to optimize the process mean of a response. Variability may be similarly optimized or jointly optimized by using a Taguchi approach. Thus a robust process window is delivered from this phase. This is the phase that must be improved to demonstrate flawless product performance and financial goals.

5. Control Phase: Control Phase provides the means to measure the improved process and to maintain the gains of the improvement. The tools used in this phase are Mistake Proofing/Poka-Yoke and SPC. The Six Sigma team will deliver an updated Process Failure Mode & Effect Analysis (PFMEA), Process Control Plans, Standard Operating Procedures, and Work Instructions. The team should also validate the measurement system effectiveness, Process Capability analysis, and targeted COPQ. Prepare the final project report, summarize the lessons learnt, and disband the project – mission accomplished.

V. Six Sigma Results

Based on the limited implementation that we have had at BD, all Six Sigma projects were successful, and a few were more successful than others were. There was a synergy among many projects, because identical products are manufactured and distributed in various parts of the world. Six Sigma training increased communication, cross culture interaction among the Black Belts. This was indeed true transformation of BD culture as one company WorldWide.

BD Supplier as a Black Belt: BD asked a key raw material supplier to send a candidate to the First Wave Black Belt training. This supplier provides printed Tyvek labels to BD. BD Incoming Inspection takes a sample and inspects for legibility, missing color, plugged image, and black spots. 52,750 samples were inspected and total 1450 defects were recorded in 1998. What is the Sigma level of the printing operations at the supplier?

$$\begin{aligned}
 DPU &= \frac{\text{No. Defects}}{\text{No. Samples}} \\
 &= 1450 / 52750 = .0274 \text{ DPU} \\
 DPMO &= \frac{\text{No. Defects}}{\text{No. Opportunities}} \times 10^6 \\
 &= 1450 / 158250 \times 1000,000 = 9162 \text{ DPMO} \\
 &= 3.86 \text{ Sigma}
 \end{aligned}$$

The supplier did inspect before supplying to BD. However, the supplier inspection was not efficient, because 0.0274 DPU escaped the inspection. If we assume the efficiency of supplier's inspection is 85%, then the calculated defects found at the supplier are: 8216 (1450*0.85/0.15)

$$\begin{aligned}
 \text{Therefore, Total defects} &= \text{Defects found at the Supplier (Calculated)} + \\
 &\quad \text{Defects found at BD} \\
 &= 8216 + 1450 = 9666 \text{ Defects} \\
 DPU_{\text{Total}} &= 9666 / 52750 = 0.1832 \text{ DPU} \\
 DPMO_{\text{Total}} &= 9666 \times 1,000,000 / 158250 = 3.05 \text{ Sigma} \\
 FPY &= 81.6\%
 \end{aligned}$$

Over 18% of the printed roll stock had one or more defects and were scrapped. Because of the high COPQ, BD offered the Six Sigma quality improvement program to the supplier.

Two Champions, one from the supplier and the other from BD were nominated. A Six Sigma Black Belt candidate was nominated at the supplier for the training. A project team, consisting of three members from each of the businesses involved and the Black Belt as the team leader, was also formed. The team selected a product line and calculated the COPQ, which was 15% of the contract price. The team set a goal to reduce it by 35%. The supplier used BD acceptance sampling data, because the printer had no data, but started collecting immediately. Major defects were identified by Pareto charting and FMEA. Next, attribute GR&R was calculated for each type of defects. BD operators also participated with those of the supplier in calibration of the measurement system.

Based upon the analysis of the data, the team recommended to measure ink viscosity at regular intervals, to use a new sticky bag every day, and to limit the printing plate impressions according to the manufacturer's recommendations. The defect rate dropped very significantly after the above process changes. Extensive samples were taken for several days and were inspected by the supplier and BD operators. No defects of any kind were found.

Encouraged by the results, the Six Sigma team decided to study the effects of four process parameters on the quality of the product by statistical design of experiments. A one-half fraction of a 2-level factorial design was run. The experiment also included three center points. A process window for the key variables was calculated and confirmed by subsequent experiments.

It was estimated that the supplier would improve the process/product that will save 25% of the COPQ against the target of 35%. Of course, this saving is recurring every year and the quality improvement will go on continuously after the Black Belt training.

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