

White Paper: Lean Six Sigma

**What is Six Sigma, What is Lean, and
How Can Lean and Six Sigma be Combined to
Lead Your Organization to Operational
Excellence and Continuous Improvement?**

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Introduction

Lean Six Sigma is on the brink of becoming one of modern business's longest lasting improvement and change management initiatives. Recently, Motorola celebrated its twentieth year of Six Sigma deployment. It has been estimated that Six Sigma has saved companies an estimated \$427 billion and that Six Sigma deployments contribute to 2% in sales per year. A further indication of the success of Six Sigma is that 53% of all Fortune 500 companies and 82% of Fortune 100 companies are currently using it (Michael 2007).

While any figures about the impact of a program such as Six Sigma are open to dispute, the fact is that, over the course of its existence, Six Sigma has shown an extremely high level of growing acceptance in many business circles. Currently, there are no signs that Six Sigma will cease to be important for process improvement in the near future. This is not to say that with all its strengths Six Sigma does not have various critiques and shortfalls. However, it is clear that Six Sigma has outlived many rival management philosophies and theories, including Management Reengineering, Service Quality, Customer-Centered Project Management, and others. One of the key reasons why Six Sigma has fared so well over the course of its history is that it has simultaneously embraced a set of core principles and elements that have persisted since its very inception at Motorola in the late 1980s and shown a high level of flexibility in adapting to and integrating alternative management philosophies, methodologies, and ideas.

The purpose of this paper is to give an overview of Lean Six Sigma that identifies both its sustained core principles and the integration of many other management philosophies, such as lean management, into its framework.

What is Lean Six Sigma and How Did It Evolve?

The term “six sigma” is used to describe three key elements of a Six Sigma program (Zu, Fredenhall, and Douglas 2005):

1. A statistical term to measure the performance of a process relative to customer expectations.
2. A set of practices, techniques, and methodologies with the end goal of bringing the process performance to a level of 6 sigma.
3. A management approach that encompasses prescriptions about effective organizational management, strategy alignment, and organizational structure.

Bill Smith, an engineer at Motorola, coined the term “six sigma” to describe the degree to which a process is capable of producing non-defective items (McClusky 2000, p. 8). A six sigma process is characterized by the fact that only 3.4 defects occur in one million production units. Thus, the ultimate goal of Six Sigma is to create six sigma capable processes.

Six Sigma As a Statistical Concept

The core idea behind Six Sigma is to reduce the number of defective outputs of a process to a level of 3.4 defects per 1 million opportunities (DPMO). Every process creates variation. Some of that variation is called a defect when the specification limit set by the client is not met. Below is a demonstration of what Six Sigma does, followed by a discussion of the historical roots of this way of looking at process performance.

The Concept of Six Sigma

A customer such as the ED medical staff may require that all Chemistry tests are to be reported within 25 minutes. If the test is reported too late, this is called a defect. In this case, we have a customer specification (the test is resulted within 25 minutes) and a defect (the test result takes longer than 25 minutes). In order to avoid confusion from the get-go, we need to clarify what is meant by the term “variation.”

Any process creates some variation. The term variation is used in three ways in the context of Six Sigma:

1. The **natural variation** in a process is also known as “common cause variation.” There will always be some variation in the analytical and pre-and post-analytical phases due to the impact of people, machinery, current methods, etc. One test may take 17 minutes from order to verification; another test using the same process may take 19 minutes.
2. **Special cause variation** is induced by special and assignable causes. For example, the tube system may be down, resulting in a delay in receipt of the specimen by the lab. Or during a shift change, an employee may be late due to a personal emergency.
3. **Defects**, also known as *rework loops*, in a production system occur when the final product does not meet the customer’s expectation. For example, this can occur in an Anatomic Pathology environment when the pathologist cannot read the slide and the slide has to be restained and resent to the pathologist for slide review. Defect is that form of variation that prevents the customer from receiving the specimen in a timely manner or in the reporting format that he/she requires. It differs from the other two sources of variation in that this form of variation is defined relative to a standard.

Variation really encompasses two very different concepts: (1) variation that is driven by the process steps in the process system and (2) the outcome of the process step. As long as the process meets customer expectations, the process steps typically do not become the center of attention of Six Sigma projects. However, when the customer complains about the outcome of the project (the quality of the report, the turnaround time to receive the slide, or the quality of the stain to support the anatomic pathologist’s effective reading of the slide), Six Sigma comes into play. In our case, the standard is set by the client at 25 minutes. Thus any variation from the standard of 25 minutes is called a defect and results in a rework from a production point of view. For example, when the anatomic

pathologist calls the Histology department to provide a restained slide, this in turn increases the turnaround of the slide production process.

The goal of Six Sigma is to reduce the variation in the process to a degree that the probability of a defect occurring is less than six sigma (i.e., 3.4 defects per million opportunity). The following discussion will clarify in much more detail what this abstract sentence really means to the lab industry.

Type of Process Variation

The standard deviation is a statistical measure of the variability of the process. In modern production management, variability due to natural forces such as men, machine, methods, and measurements of the current process setup is captured in a Shewart control chart. Shewart control charts should be familiar to most clinicians because they set the foundation for the Westgard rules. In Six Sigma in clinical production systems, the usage of control charts is extended to the pre- and post-analytical processes that also create defects in the production system. In the analytical process, the control charts are well established using the Westgard rules. By applying Shewart charts to lab pre- and post-analytical processes, the lab industry has had to make a shift in perception and apply principles that have been applied for a long time in an *analytical* setting to a *pre- and post-analytical* setting, no matter what the exact focus of the operation is—Chemistry, Anatomic Pathology, Microbiology, Serology, Hematology, etc.

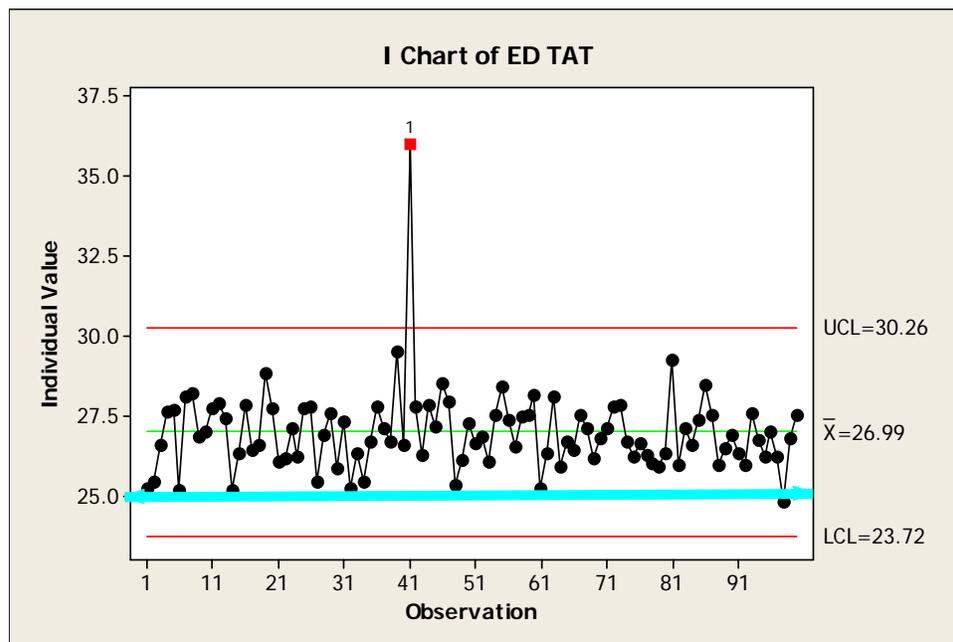
Before going into a detailed discussion of what Six Sigma does, it is best to further elaborate on the example of turnaround time and clarify step-by-step how a six sigma capable process is developed given a current baseline using Shewart control charts and applying the three types of variation discussed above to a real-life setting in a pre-analytical and post-analytical context.

The Shewart control chart (1933) was developed to graphically represent how natural cause variation and special cause variation operate in a process. Through a simple technique, the Shewart control chart also shows the defect rate and how the defect rate relates to the other two sources of variation. In the first step, the Shewart control chart calculates the average performance and how many tests meet or exceed the natural control limits of the process. The range of the natural control limits gives a good indication of the mean of the process, the control limits (what is the variation distribution 99% of the time), and the special cause variations. Secondly, the special causes are identified. Special causes typically constitute 1% of the total variation because these are the data points that can be expected to occur if nothing would be done to the process. Next, the defect rate is depicted. For this purpose, an additional line in the control chart shows how the current mean and natural variability relate to the customer. In other words, by looking at the data point outside the specification limit (determined as 25 minutes' time from order to verification), the manager gets a quick view of how good or bad the operation functions at that point in time. Special or assignable causes are under the control of the manager. They may occur because some special and extraordinary event occurred during the operation (tube system down, extended break, etc.). These are the kind of issues that are to be discussed with employees by their immediate supervisors

in a regular forum. For example, FedEx spends five minutes at each shift change to discuss the special cause variations of the previous day.

Figure 1 shows a process that has an assignable cause (red dot above the upper control limit), which was identified as an analyzer having a short break-down. In addition, the chart shows natural variation depicted between the upper control limit (upper red line, UCL = 30.60) and lower control limit (lower red line, LCL = 23.72). You will also see that the process is almost not capable of meeting the ED's expectations because most of the data points exceed the 25-minute turnaround time (blue line).

Figure 1: Defect Rate, Natural Variation, and Special Variation in One Chart



It should be mentioned and clearly emphasized that the improvement of a process in a lab environment requires two types of intervention, as discussed in the following paragraphs. The overall goal of process improvement is primarily to reduce the number of defects, i.e., variation from the standard.

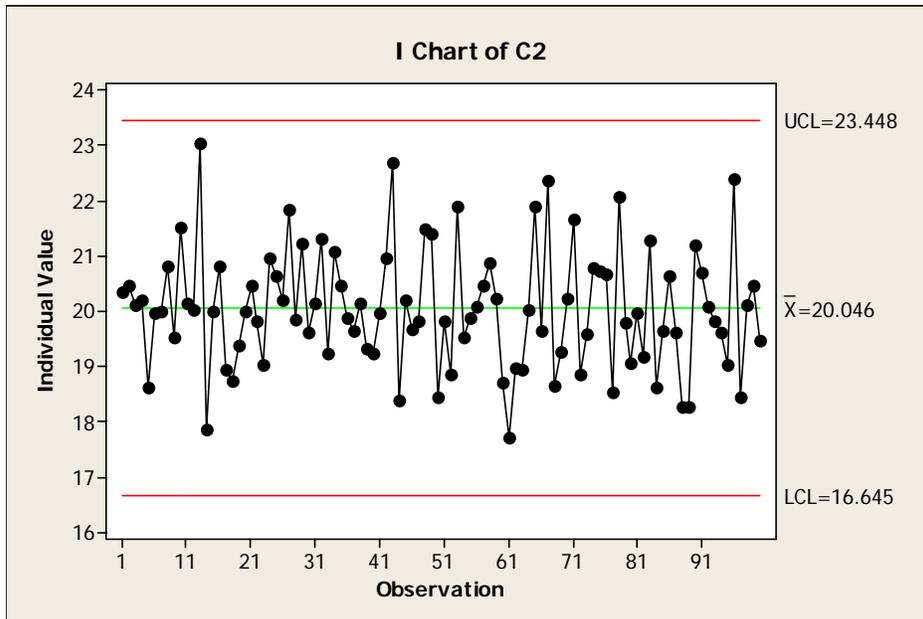
First, special cause variations should not be improved through large-scale interventions. Labs are notorious for creating special processes or workarounds to improve a one- or two-time occurrence and mitigate a defect rate that is clearly assignable to this cause. If the process changes, engineers call this "tinkering with the process." A good way of dealing with these special causes is to make them the debate of daily operations meetings to clearly identify the root causes of the problems and then tailor an intervention right to this special root cause.

The process improvement methodology of Six Sigma proceeds by analyzing the natural variation of a process (common cause variation) to determine to what degree a current process is capable of meeting the customer's requirements. The goal of process improvement is reduce the variability in a process to ensure that the process is

consistently capable of meeting the customer's requirements. First, the special causes are identified and removed to make the process stable and predictable. Then, the vital few factors that impact the performance are identified, and interventions are tailored towards reducing the portion of the variation to reduce defect. One misunderstanding should be clearly discussed at this point. It is not the goal of Six Sigma to simply reduce variability but to reduce variability to the degree that it makes the defect rate 3.4 defects in one million opportunities. Further improving the process leads to costs that do not add value to the customer. Figure 2 shows a control chart that depicts a process that is stable, shows lower levels of variability than the original process, and meets customer needs. In other words, it is six sigma capable. A six sigma capable process is determined by four factors. The fourth factor will be discussed in the next section.

1. The process shows no assignable causes, also called outliers.
2. The process operates continuously within the expected 25-minute turnaround time set by the ED client.
3. The natural variation of the process is well within the expected 25-minute turnaround time set by the ED client.
4. The process allows for what is called a "1.5 sigma shift." This shift indicates that over the long-term the process will show higher levels of variation than in the short-term, and the 1.5 sigma shift takes these shifts in common cause variation into account in order to "buffer" the process from ever exceeding the targeted six sigma level of 3.4 defects per 1 million opportunities.

Figure 2: Process That is Six Sigma Capable and Shows No Special Cause Variation



Note that the process control limits are now lower than the process specification limits. While the natural variation of the process is now between 16 and 23 minutes and the specification limit (expectation) is 25 minutes, the control limits are much lower than the specification limits, and the average is way below both the control and specification limits. This is what you want to achieve with a six sigma capable process. The process is

in control, shows no signs of assignable cause variation, meets the needs of the customer, and allows for long-term variation without impacts on the defect rate.

Figure 3 shows another way of looking at the goal of Six Sigma. Table 1 follows with a review of the key terms, their meanings, and how they translate in a lab environment.

Figure 3: The Basic Ideas of Six Sigma

Process Output Categories

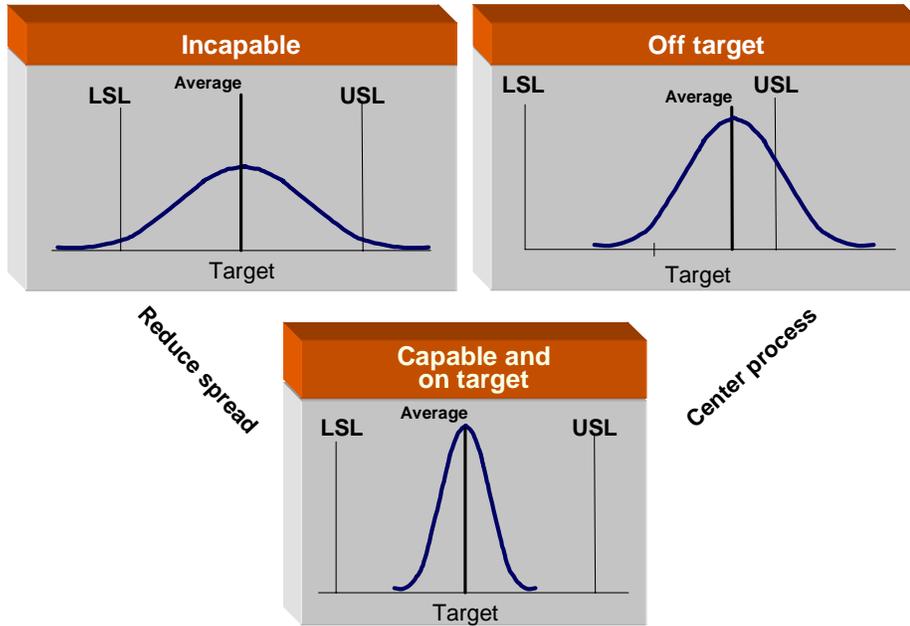


Table 1: Key Terms Regarding Variation

Name of Variation	Meaning	Example
Common cause variation	“Natural” variation that occurs because of fluctuations in the process.	Variation due to normal volume, time spent in the machine, etc.
Assignable cause variation	Special occurrences in a process.	Tube system is down resulting in increased time from ED ordering to specimen receipt at the lab.
Specification limit	Required expectation of the process set by the client.	ED may require that regular Chemistry tests have a turnaround time of less than 25 minutes.
Defect	Any variation in a process that exceeds the customer’s set expectation.	A test that takes longer than 25 minutes, no matter if this is a one-time occurrence or a regular occurrence due to the current capability of the process.
1.5 sigma shift	A long-term shift in performance that has an impact on defect rates in the short run.	Within two weeks, process performance may be expect to be x. In the longer run (e.g., two months), there may be a fluctuation of performance by 1.5 sigma above or below the baseline.

One of the big points of contention in Six Sigma is the fact that the 1.5 sigma shift is not very well understood. The following section summarizes the rationale and evidence provided for the assumed 1.5 sigma shift.

History and Empirical Evidence of the 1.5 Sigma Shift

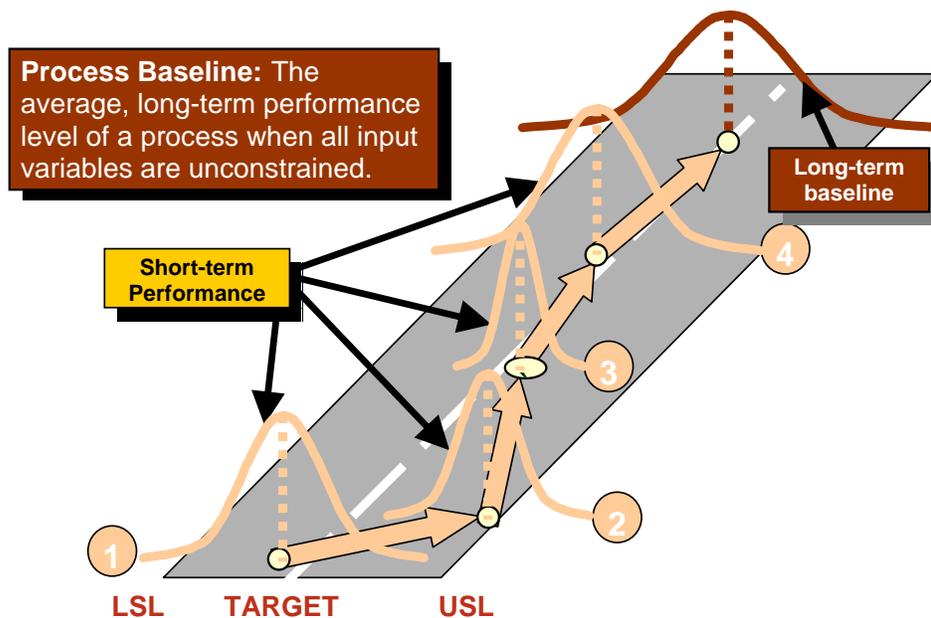
The goal of Six Sigma is in essence the same as that of total quality management (TQM): produce defect-free (i.e., quality) products and services. Both Six Sigma and TQM focus on the voice of the customer to determine the quality requirements for products and services. Based on this information, TQM developed two concepts to determine to what degree a process is capable of meeting the customer requirements: process variability and process capability. The key difference between TQM and Six Sigma is in the determination of process capability.

As mentioned above, Six Sigma shares the same ultimate goal with Total Quality Management (TQM). However, where TQM and Six Sigma differ is in the ultimate measure of process capability. Contrary to TQM, Six Sigma believes in a “six sigma capable process.” This idea originated in an observation made by Bill Smith at Motorola around 1985. He noticed “sudden shifts” in process averages that were ignored in the control charts used by the proponents of TQM. He found typical shifts on the order of 1.5 sigma. Under normal situations, this would immediately have been recognized as being the result of a special cause. That is, sudden shifts in a process are the result of a change, an abnormal event. Whether attempts were made to remove these special causes is lost in history. Perhaps the cause could not be removed, such as in the instance of raw material from two different suppliers. Whatever the cause, it was decided to make an allowance for these “sudden shifts” by broadening the specification limits.

In 1985 Mikel Harry linked up with Bill Smith at Motorola. Between 1985 and 1988, Harry developed a theory to try to explain the shifts in process averages and how the overall errors in assembly are affected by the errors in components. In his work, Harry referred to two papers published in the 1960s and 1970s (Bender 1962 and Evans 1975), which include discussion of standard deviations or shifts in component assembly. In developing the Six Sigma tables, Harry determined the quality of a stack of disks and how the overall error in the size of the stack relates to errors in the individual disks.

Thus was born the idea to measure quality not in terms of percentages but in terms of conversion tables that would adjust for the 1.5 shifts that one can expect a process to experience in the long run. Adding this 1.5 shift to the sigma led to the idea of setting a goal for process improvements that result in a six sigma capable process. With this level of performance, a process could expect to only produce 3.4 defects per one million opportunities and experience a 1.5 shift (Harry and Schroeder 2000). The following figure demonstrates what is meant by a 1.5 sigma shift.

Figure 4: 1.5 Sigma Shift



At the time that Bill Smith and Mikel Harry developed the idea of a sigma measure, Motorola went through a major transformation phase that heavily emphasized quality and training. In this context, the group around Bill Smith and Mikel Harry made additional changes that would ultimately lead to the evolution of Six Sigma not only as a goal for quality, but as a quality initiative that differed in significant ways from its predecessor TQM.

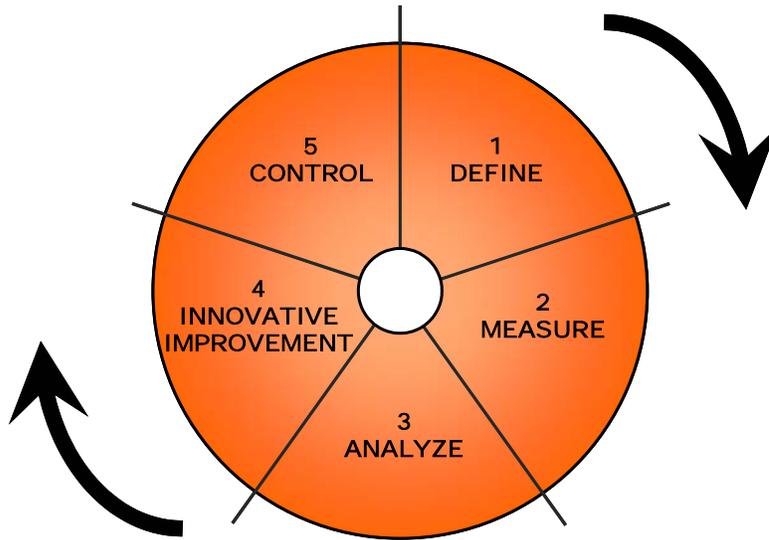
Once the goal was clearly established, quality engineers at Motorola developed internal programs to accomplish these goals. It should be noted that the ultimate shape of Six Sigma in its four facets—statistical measure, improvement methodology, organizational structure, and management philosophy—were the result of at least six years of experimentation with changes within the different divisions of Motorola. The adaptation of other improvement philosophies such as lean production can partly be attributed to the fact that Six Sigma was the result of an evolution within Motorola and beyond. While it is difficult now to fully reconstruct the exact historical path within Motorola, it is clear that, at the end of the process, what started out as a quality improvement initiative ended up in an integrated strategic approach to business process improvement now called Lean Six Sigma.

Lean Six Sigma As a Methodology

One of the first changes in practicing quality improvement projects that occurred was in the general methodology employed in order to achieve the six sigma goal. It became clear from the very beginning that quality initiatives often fail because the scope of the project is poorly defined. As a result, the Plan, Do, Check, Act cycle was altered into a

five-step methodology that added a Define phase. The Define phase ensured that quality groups' projects were clearly defined and communicated to key stakeholders and the organization. As a result, all Six Sigma process improvement projects now follow the five-step model: Define, Measure, Analyze, Improve, and Control, or DMAIC (Pande, Neuman, and Cavanagh 2000).

Figure 5: DMAIC



1. In the Define phase, the project leaders are required to complete a project charter and a high-level process map that helps to establish the boundaries of the process to be improved and determine the customers and stakeholders. Based on this information, the “Critical-to-Quality” characteristics of the process are defined as set by the customer. “Critical-to-Quality” in an ED setting would be accurate results about the correct patient retrieved within 25 minutes of ordering.
2. In the Measure phase, the Six Sigma improvement team creates a detailed process map identifying all of the inputs and outputs at each process step. Following this exercise, the measurement system is established using in many cases a measurement systems analysis (MSA) to determine criteria of repeatability and reproducibility of the measurement system. Finally, the current state defect rate is established and the base sigma score calculated.
3. In the Analyze phase, the root causes of the process variation are identified and, if possible, quantified. Depending on the complexity of the project, simple root cause analysis tools are used, such as the fishbone diagram or the “5 Why” technique. On the other end of the spectrum, designed experiments or experiments based on Taguchi or Shainin principles are conducted (de Mast 2004).
4. In the Improve phase, the key root causes of process variability are translated into improvement interventions. Sophisticated experimental techniques are also advocated in this phase in order to ensure that the improvement recommendations truly work.

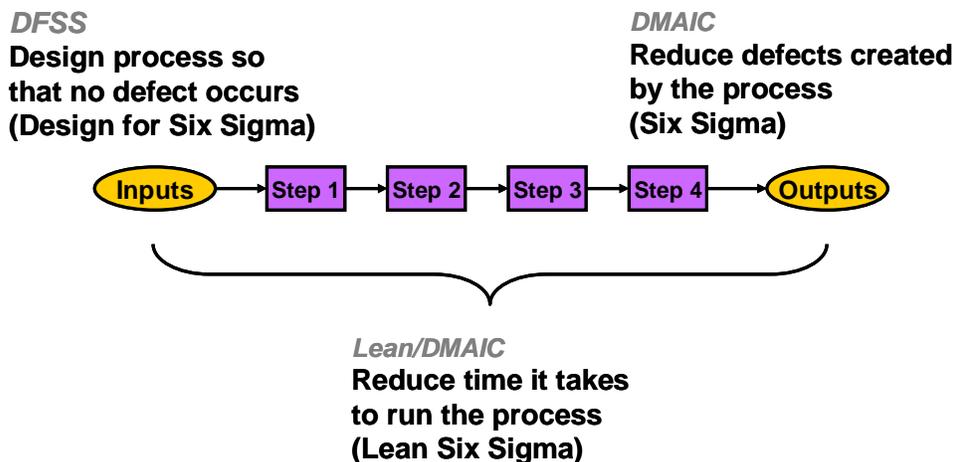
- In the Control phase, the new process performance is monitored for a certain period of time, which is followed by the establishment of a control system that is then handed back to the process owner.

While there are differences among practitioners in regards to the exact tool usage in each phase, the “toolkit” itself has been incorporated into a body of knowledge that is well-documented and used for certification purposes. The guidelines set by the ASQ are the primary guidelines currently used worldwide (Breyfogle 2003 and Pyzdek 2001).

In instances where no processes exist or processes need major reengineering, Six Sigma developed a framework called Design for Six Sigma (Eckes 2001). Here, the Improve and Control phases are replaced with Design and Verify (DMADV - Define, Measure, Analyze, *Design*, *Verify*). An alternative approach used in the application of Lean Six Sigma principles for facility design uses the acronym DMAVI, which stands for Define, Measure, Analyze, Verify, and Implement. In the case of a facility design, the verification of the validity of the design is so long and the process involves so many parties and hand-offs (lean designer → architect → engineer → construction agency) that a verification of the effectiveness of a lean facility design takes a long time, unless it is a shorter project involving partial facilities redesign. Design for Six Sigma was developed after the DMAIC improvement methodology had been fully developed starting in the mid-1990s.

Starting in the mid-1990s Six Sigma also started to incorporate lean production methodology as advocated by Womack (1990). Thus, currently Six Sigma uses three types of methodology: DMAIC Six Sigma (process improvement), Lean Six Sigma (waste reduction and cycle time improvement), and DFSS Six Sigma (product design). The attached figure shows how Design for Six Sigma, DMAIC, and Lean are all interrelated in the improvement of the process. DFSS starts at the input side. DMAIC focuses on the output side, but lean looks at the throughput of the process. Combined, the Lean Six Sigma methodology allows for the synergies of all three methodologies in a pragmatic manner.

Figure 6: DFSS, DMAIC, and Lean



What is interesting about Six Sigma as a methodology is the fact that it did not invent any new methods. Rather, Six Sigma has adapted the different “tools” already available and sequenced them in a way that more or less fits the five problem-solving steps. This lack of invention of new process design or improvement tools is one of the main reasons why many professionals view Six Sigma as not being fundamentally different from TQM. On the other hand, it has given Six Sigma a wide flexibility in solving various problems for an organization. Currently, Six Sigma is in the process of adapting tools developed in other areas, such as marketing research or data mining, and adding to its “toolkit.”

Lean Six Sigma as an Organizational Structure

Besides the adaptation of various problem-solving methodologies, Six Sigma has also developed its own unique deployment strategy, including a Six Sigma organizational structure or framework. Prior to Six Sigma, quality improvement efforts were primarily conducted by quality circles, which had been invented in Japan. The challenge with these quality circles is that they are established on a more or less ad hoc basis and they often dissolve when organizational priorities change. In order to ensure that Six Sigma projects get continuous support, a new type of quality expert system was developed.

One anecdote has it that Mikel Harry had a conversation with a plant manager in Utah who told him that “we’re kicking the heck out of variation” in production. A martial arts metaphor then surfaced in their conversation, and the idea apparently caught on and was first published in 1995. As a result, Six Sigma experts have been categorized into layers and referred to as various color “belts” (Harry and Schroeder 2000). The following pyramid shows the various levels of organization engagement.

Figure 7: Pyramid of Lean Six Sigma Organization



- At the highest level is senior leadership, called the **Champion** in Six Sigma. These are executives in the organization that ensure that the right projects are selected, see that resources are made available, decide on the scope of the project, decide on the team composition, and in general articulate the importance of the project to all stakeholders in the project.
- Next, there are **Master Black Belts** who are trained in all aspects of Six Sigma, including deployment and the statistical, lean, and other tools used to improve or design processes.
- Master Black Belts in turn train, coach, and mentor so-called **Black Belts** who are the project leaders of Six Sigma improvement projects. These Black Belts go through three to five weeks of intensive training and apply their skills by improving two to five projects with high defect rates annually. Smaller projects are executed by **Green Belts** who go through a training program lasting between one or two weeks.
- Finally, in recent years **White Belts or Yellow Belts** have been advocated to work projects in smaller organizations (Adeyemi 2003).

Each layer has its certification. The training for the various expert groups has been standardized and results in certification. While various organizations are different in their training curricula, the current standard for certification is the ASQ. Part of the reason why Six Sigma is so adaptable and flexible is due to the fact that up until the late 1990s no professional quality organization took the lead in setting certification standards. ASQ only got involved after Six Sigma became such a success and it became clear that organizations were moving away from deploying TQM programs.

You will see from the above figure that employee buy-in sets the foundation of the enterprise-wide organization. Without the mutual understanding of management and employees about the value of Lean Six Sigma, deployment will not be successful. Thus, involvement of employees, communication, and adequate recognition for success are mandatory for an effective deployment of Lean Six Sigma.

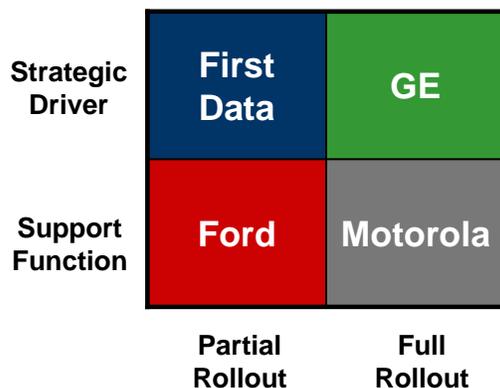
Lean Six Sigma Deployment, Leadership Support, and Tying Lean Six Sigma to Corporate Strategy

While the practicing core of Six Sigma professionals adheres very closely to the statistical, methodological, and organizational prescriptions of a successful Six Sigma initiative, less consensus exists regarding the deployment and the link to strategy. Here is where organizations may differ dramatically in what they call a “Six Sigma initiative.” As discussed earlier, Six Sigma was never a “finished program” from its very beginnings at Motorola and has gone through major transitions throughout its twenty-year history. At Motorola, Six Sigma was still very much embedded in the philosophy of TQM. This changed when Jack Welch adopted Six Sigma in 1995 and announced Six Sigma not only as a way of doing business but also as a key driver of GE’s corporate strategy. As a result, not only key quality metrics were improved through Six Sigma, but the entire organizational financial performance also became interwoven with the various Six Sigma

initiatives during the mid and late 1990s. At one point, GE gave the impression that Six Sigma almost absorbed corporate strategy. As a result, we are now faced with Six Sigma deployments that range from an emphasis on classical quality improvements using critical Six Sigma metrics, methodologies, and organizational structures to very ambitious Six Sigma deployments whose primary focus is the relentless pursuit of quality and financial excellence.

A second dimension that makes it difficult to talk about “the one best way” to deploy Six Sigma is the fact that Six Sigma can be implemented centrally as was done at Motorola or GE, or decentrally as is often the case when individual business units implement Six Sigma but the initiative is not fully rolled out through the entire organization. GE was successful in setting a benchmark for Six Sigma deployment. Using GE’s model, Six Sigma is rolled out through the entire organization, drives the corporate strategy and profitability, and fundamentally changes the culture of the organization. Typical elements of the GE deployment model are goals set at specific targets, such as training 1% of the total employee base as Black Belts or tying project improvement goals to targeted financials such as savings or revenues of about \$250,000 per Black Belt project. The GE deployment model is based on very rigid metrics driving a deployment plan that allows individual business units to make changes to their deployment plans as long as the overall corporate targets are being met. Motorola on the other hand had the less ambitious goal of developing almost zero-defect quality and to acquire the Malcolm Baldrige award in 1991. As a result, the Six Sigma deployment at Motorola was more flexible and less driven by set matrices mandated by the executive management team.

Figure 8: Six Sigma Deployment Strategies



Interestingly, the GE model has received more attention than other potential deployment strategies, and most consultants and practitioners advocate and still think within the parameters of some kind of a watered-down version of the GE model (see Eckes 2001, George 2003, Snee and Hoerl 2003). In this version, the goal of the deployment plan is to align Six Sigma with key strategic initiatives and to ensure that all completed projects support the strategic goals of the organization. Consultants typically prescribe a high-level process map that outlines the various core processes and then prioritizes those areas that have the highest probability of success. As a next step, key executives are identified and trained in their role as future agents of change. Subsequently, Black Belts and Green Belts are trained and key projects executed. A full strategic analysis of the competitive

forces in the industry may or may not be part of the assessment that leads to the Six Sigma deployment plan (Snee and Hoerl 2003).

Conclusion

Starting in the mid-1990s, process improvement has continuously combined principles developed under the umbrella of lean, waste reduction, and Six Sigma to improve customer satisfaction, employee morale, and bottom-line performance. The way that these highly effective methodologies are being deployed vary from company to company and from industry to industry. While some companies roll out Lean Six Sigma across the entire organization, others deploy Lean Six Sigma across company sub-units. There is no one best way of deploying Lean Six Sigma, and companies are advised to use a deployment strategy that best aligns the improvement effort with the general strategy of the organization. By encompassing a pragmatic blend of methods that drives out waste and reduces defects as perceived by customers, Lean Six Sigma has become an integral tool that successfully transforms organizational culture and sets organizations on a path to relentlessly pursue perfection and achieve operational excellence.

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