



Creative Healthcare



LEAN & SIX SIGMA: the new face of Performance Improvement in Pharma

In the popular film, *City Slickers*, Billy Crystal learns the secret to life is “one thing,” and the purpose of his life is to discover it. His character in the movie proceeds to survive one trial after another, in pursuit of this elusive but important goal. This same thinking is embodied in the philosophy of Six Sigma, a performance improvement methodology suggesting that “one thing” (called a “critical x”) is likely the key to improving performance and, once identified, organizations can literally turn the dial to achieve whatever performance is desired. Six Sigma was introduced first in the field of heavy manufacturing, later in the service sector, and most recently in the pharma sector.

If Six Sigma is about those “critical few” process variables that affect performance, then Lean methodologies can be described as focussing instead on the “trivial many.” Indeed, Lean is all about finding waste in process design, often by classifying those steps that are “value added”

from those that are not. Non-value added activities abound in most organizations, and Lean weeds these steps out of a process to make products and services more efficient.

In the past year, Six Sigma and Lean conferences have permeated the pharma landscape like no other performance methodology before it. Conferences that examine Six Sigma’s impact on sales & marketing, distribution, discovery and devices are available to those seeking to learn more about this presumed “holy grail” of performance improvement. Merck, Baxter, GlaxoSmithKline and J&J have all initiated Six Sigma and Lean programs, with varying degrees of success. But as many pioneering organizations have found, Six Sigma and Lean are not for everybody, and implementation can bring many challenges that must be overcome before benefits are realized.

SIX SIGMA EXPLAINED

Six Sigma is a performance improvement methodology that seeks to identify the key sources of variation in a process (“critical x’s”) that cause defects to occur. By mapping processes, measuring their output, and analyzing its many input variables, Six Sigma determines how to optimize the output from a process by controlling the inputs. Six Sigma projects move through a disciplined framework (known as “DMAIC”):

Define the problem – in terms of performance, consequences and gaps from what is desired

Measure the process – first to ensure the data is reliable, then to decide how well the process performs

Analyze the variables – using statistical tests of significance, to find those variables that have the greatest impact on process yield

Improve the process – through small scale experiments and hypothesis tests to compare the impact, before and after

Control the process – to sustain gains and ensure process does not regress to previous levels

The term “Six Sigma” refers to the level of perfection such a process will deliver. Specifically, a “Six Sigma process” allows for six standard deviations between the average performance of the process and its nearest specification limit. This process will produce defects only 3.4 million times per million occurrences (3.4 DPMO) and is regarded for all practical purposes to be “a perfect process.”

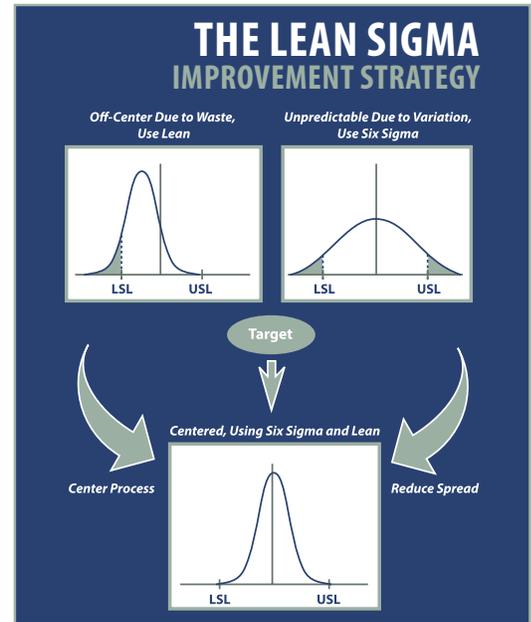
Sigma	Defects per million opportunities
1.5	500,000.0
2	308,537.0
3	66,807.0
4	6,210.0
5	233.0
6	3.4

Source: Jean Cherry, Sridhar Seshadri, “Six Sigma: Using Statistics to Reduce Process Variability and Costs in Radiology,” *Radiology Management*, Nov/Dec 2000

OLD WINE, NEW BOTTLES

The origins of Six Sigma and Lean are a testament to their tenacity. In fact, application of statistical analysis to the improvement of yield dates back to when the U.S. was an agricultural-based economy, and yield in crop production was expanded exponentially to serve a growing population from a finite amount of production capacity. After WWII, the Japanese adopted many of the same principles, combined with a fierce focus on quality, to compete against their American counterparts in automobile production and other engineering related fields. American manufacturers learned the hard way that their processes were far from efficient when Asian economies began to erode market share, business that was previously presumed to be a perpetual pipeline.

Six Sigma’s appeal lies not only in how it can leverage data; but also in the very disciplined framework it offers for problem management, often leading to projects that can take several months to complete (see inset). In Six Sigma parlance, it’s all about “fixing the problem for the last time.” Lean, on the other hand, intends to quickly weed out the low hanging fruit from processes that suffer from wasted motion, redundant steps and unprofitable activities. Taken together, processes can be streamlined, cycle times compressed, and variation nearly eliminated, creating more predictable processes that meet customer requirements every time.



ONE STEP AT A TIME

However, not all companies take such a holistic approach to performance improvement. Given the scope of learning required to master either set of techniques, most companies initially will take on either Six Sigma or Lean as the main focus of their improvement efforts. “Our focus is not on improving a process already regarded as non-value added,” notes John Wilmoth, Production Project Manager for the Consumer Products Division of Alcon Manufacturing, Ltd. “That is why we tend to use Lean most often. We examine our processes and eliminate as much waste as we possibly can. After doing so, we might return to a specific process later to see if some Six Sigma techniques might be of value.”

Wilmoth describes a simple Lean project that demonstrates the value of identifying waste in the value stream of production. Alcon produces a surgical product for a Japanese customer that has very specific packaging requirements. Due to the complexity of these requirements, Alcon was dedicating four successive shifts to the creation of one batch of production. By creating a Value Stream Analysis, Alcon was able to reduce redundancy in inspections, shift labor to match product flow down the line, and reduce production from four shifts to one. One FTE was redeployed simply by putting a mirror on the production line, allowing one inspector to see both sides of the product, whereas before one inspector stood on each side. “We saw a significant savings as a result of our changes,” notes Wilmoth.

Pharma lab environments are ripe for Six Sigma and Lean since they are rich in processes and often depend on batching of supplies and production, a process that is inherently

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LEAN EXPLAINED

Lean methodologies do just what they say, they “lean” out a process by eliminating waste. Various estimates have been provided regarding the amount of waste in manufacturing processes, these range from 20-30%. Recent studies have put such waste in economic terms, suggesting that for every 10% of wasteful activity eliminated, companies will enjoy a 2.5% boost in operating income.

Lean eliminates waste first by creating a “value stream analysis” of every step in the process. Steps are deemed “value added” only if they (1) materially impact the unit of production moving through it, (2) that step is valued by the customer and (3) it is done properly the first time, with no need for rework. A variety of additional techniques are available to support Lean projects, as described further in this piece.

EIGHT TYPES OF WASTE

- Defective Products and Services
- Excessive Motion
- Overproduction
- Excessive Processing
- Excess Inventories
- Transportation
- Not Leveraging Human Resources
- Waiting

ONE STEP AT A TIME (CONT.)

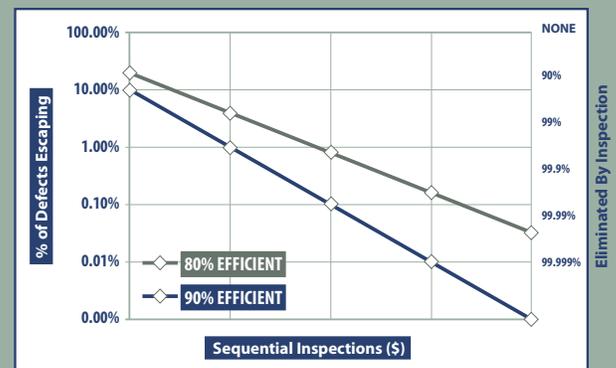
wasteful as it causes companies to stockpile inventories, delay flow of finished goods, and cause inefficient use of resources. That was certainly the finding made by Blood Systems Laboratories, one of the largest blood testing facilities in the U.S. BSL runs about ten tests on each sample of blood, and with 2.6 million donors annually, that equates to 26 million repetitions of processes, not including the many back-office functions necessary to support the operation.

BSL’s processes are similar to many in the pharma space; in this case a unit of production is an acceptable unit of blood. Failures of tests, missed inspections, incomplete documentation can all result in failure of an entire batch of product. One of the more common projects at BSL, for example, is the prevention of “nonuseables.” This can take many forms in pharma; BSL has run three such projects in the last two years. One project found three “critical X’s” in the Viral Marker lab: the presence of preventable errors, empty testing wells, and contaminated sterilization fluids. By addressing these problems they reduced nonuseable runs by approximately 38% and saved the lab \$40,000 per year. The company estimates it has saved over ten times this amount from all Six Sigma projects combined.

“We have not found many places where we could not use Six Sigma,” notes Larry Morgan, BSL Director of Performance Improvement, “And the methodology really appeals to our staff, most of whom come to us with a strong technical background.”

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CAN WE INSPECT OUR WAY TO SIX SIGMA?



Inspection takes many forms in pharma: visual analysis, record review, audits, and walkarounds, and yet Six Sigma regards inspection as fundamentally unproductive and “non-value added.” In addition to the fact a process should be improved to make inspection less prevalent, it is clear that the cost and time required to inspect and fix problems is beyond what most customers would pay, if given the choice. As the chart demonstrates, 5 or more sequential inspectors would be needed to guarantee Six Sigma performance, since the average inspection station captures only 80-90% of defects present.

BSL embraced Six Sigma shortly after emerging from an FDA consent decree, where management wanted a quick shift from a mentality of regulatory compliance to one of continuous improvement. That shift appears to be well under way at BSL, where 34 total projects have yielded, so far, a total of approximately \$400,000 in annual savings. The experience at BSL was so successful, it was expanded last year to the company's national donor centers, where 40 additional staff have been enrolled in the training program.

SHAKEN, NOT STIRRED

One of the most ambitious "Lean Six Sigma" programs can be found at Cardinal Health, the \$75 billion supplier that employs more than 50,000 people worldwide. Twenty percent of Cardinal Health's workforce can be found in their Pharmaceutical Technologies and Services (PTS) segment, which provides pharmaceutical development, manufacturing and packaging services to the pharma and biotech industries. The combined Lean Six Sigma program grew out of a corporate-wide effort to integrate Cardinal Health's sprawling business, which included about 100 acquired companies. William P. Owad, Jr., Senior Vice President of Operational Excellence, oversees the program. "Our customers made it clear that they wanted their business across Cardinal Health to be seamless," recalls Owad. "Not only will Lean Six Sigma help us to achieve uniform processes, but they will take that to the next level by reducing defects, improving yield, and ensuring on-time delivery."

To achieve such an ambitious goal, Owad needs to establish a robust Lean Six Sigma infrastructure; so far he has over 700 employees trained as various "belts" in Lean Six Sigma, thirty percent in their PTS segment. "By 2007," predicts Owad, "one percent of our employee workforce will be trained as Six Sigma 'blackbelts' and 5% as "kaizen" leaders and greenbelts." Blackbelts are typically dedicated to Six Sigma project work while greenbelts and kaizen leaders use the techniques as part of their current area of responsibility.

Owad knows that this investment must yield significant returns, and so far, he has not been disappointed. After reviewing results from 120 completed projects, the company confirms significant improvements in yield, cycle time, and on time delivery from

those processes affected. And some of the benefits they have not even attempted to quantify today, such as those that will result in future revenue streams that cannot be captured today, and therefore not guaranteed.

In spite of the promise of the Cardinal Health program, Owad acknowledges the process has involved a steep learning curve. "Going forward, we need to do a better job of matching resources to projects, to improve our understanding of customer requirements, and to leverage more Lean activities where quick wins are there to be claimed." Once Cardinal Health turns that corner, predicts Owad, they will engage more customers in Lean Six Sigma projects to fully engage the value chain.

Most companies acknowledge that their journey to Six Sigma was made easier with the use of outside consultants. "This is not the kind of thing you want to do completely on your own," warns Morgan. BSL retained a consulting firm not only for training, but to run their first project. "We thought it would be best to see how this is done, rather than to learn it from theory," he recalls. "And in the end we enjoyed the benefits from a pretty important project, which reduced the cycle time and variation for deliveries to our top ten customers."

MAKING THE GRADE

Whatever the motivation to consider Six Sigma and Lean, it is apparent these methods are here to stay in pharma. In addition to making good practical sense, pharma companies are looking at shrinking profit margins due to expiring patents, increased competition, and an FDA that seeks precisely what Six Sigma delivers: variability reduction. Additionally, various regulatory agencies and public watchdog groups are increasingly asking for more "evidence-based" decision-making that is at the very foundation of Six Sigma, just as purchasers are increasingly demanding Six Sigma level expertise from their suppliers. All of this is happening during a dramatic shift in how drug discovery will be conducted going forward.

Indeed, "making the grade" today may be as simple as harvesting the profits from a blockbuster drug, but with designer drugs, genomics and a new frontier of technologies on the horizon, drug companies must determine how to improve their processes in order to remain competitive. In the field of performance improvement, there are no rewards for complacency, being the last to adopt, or asleep at the switch.

YOU GET OUT WHAT YOU PUT IN

A typical Six Sigma project can save as much as \$500,000 in its first year – an investment that pays for itself. And while a recent survey reported that companies investing less than \$500,000 were still likely to break even, it also noted the fact that those dedicating \$2 million or more reported returns as high as six times the investment. In fact, the relationship between investment and returns is exponential in nature. The bottom line for companies investigating Six Sigma: the more you put in, the more you get out (Source: iSixSigma.com).

For the top 20 questions people have about Six Sigma and Lean, go to www.creative-healthcare.com and click on "20 questions."

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