SIX SIGMA
Quality Improvement Programs

Implementing **A SIX SIGMA QUALITY IMPROVEMENT PROGRAM** is not a magic pill to instantly improve business performance. Instead it **IS A STRUCTURED WAY TO IMPROVE THE PRODUCT OR SERVICE DELIVERED** to customers while improving business efficiency.

The Six Sigma quality improvement program has proven its value in manufacturing circles since the 1980s. Soon after, executives realized the methodology could be applied to any repetitive process, not only manufacturing, but also those in the transactional or service industries. Now, Six Sigma quality initiatives are becoming entrenched in the developmental side of the pharmaceutical and biotechnology industries as well.

According to Jim Volpe, global director of quality improvement at i3, companies introduce Six Sigma programs to make significant gains in operating efficiency and overall quality and to improve all processes by evaluating the characteristics and needs of customers and employees. A Six Sigma quality improvement program is usually explained as a measure of quality and a process for continuous improvement.

JIM VOLPE, GLOBAL DIRECTOR OF QUALITY IMPROVEMENT AT I3, SAYS IT IS EASY TO UNDERSTAND HOW A QUALITY IMPROVEMENT PROGRAM THAT TRACKS PROCESS DEFECTS AND SEEKS TO SYSTEMATICALLY REMOVE THEM WOULD BENEFIT ANY MANUFACTURING BUSINESS — WHETHER IT'S AN ASSEMBLY LINE THAT BUILDS AUTOMOBILES OR ONE THAT CREATES AND PACKAGES MEDICINES. HE DISCUSSES HOW THESE SAME PRINCIPLES CAN BE APPLIED TO THE ENTIRE PHARMACEUTICAL LIFE CYCLE — FROM RESEARCH TO APPROVAL TO COMMERCIALIZATION.

A Six Sigma business management system uses data to show how the business is meeting customer requirements.

A MEASURE OF QUALITY

"Six Sigma was designed as an effective, consistent way to assess and compare performance across a variety of departments and processes," Mr. Volpe says. "The primary purpose of a Six Sigma score is to track defects against the customer's requirements; it is a statistical measure to classify where the process falls against the customer's expectations."

A sigma value typically falls between 0 sigma (933,000 defects per million opportunities or a 6.7% yield) and 6 sigma (3.4 defects per million opportunities or a 99.9997% yield) — a near-perfect level. The higher the sigma value, the greater the probability the process will consistently meet the customer's needs. Thus, a 4 sigma process meets a customer's requirements better than a 2 sigma process. The goal is to strive continuously for a 6 sigma process.

"Once companies measure how a process is performing against customer requirements, they can focus on improving the sigma value of a process," Mr. Volpe says. "Six Sigma focuses on continuously improving processes benefiting customers, employees, and the business."

A PROCESS FOR CONTINUOUS IMPROVEMENT

Six Sigma uses a structured problem-solving methodology for continuous improvement, known as the DMAIC process. DMAIC stands for define, measure, analyze, improve, and control.

DEFINE: What is the problem?

MEASURE: How often does the problem occur?

ANALYZE: When, why, and where does the problem happen?

IMPROVE: How can the process be fixed?

CONTROL: How can problems be kept from recurring?

According to Mr. Volpe, the DMAIC methodology focuses business managers on their processes and their data. It provides the opportunity for team members to step back from their daily activities and use consistent tools to evaluate what they do every day against what is important to the customer.

"I have seen benefits in having employees in the transactional/service environment explain to the group what they do every day," Mr. Volpe says. "Using simple tools to create a process map, inconsistencies become obvious between similar employees with the same job description and how differently they perform their duties. Often, many costly rework loops or non-value added steps also become apparent."

Mr. Volpe offers a real-world example of Six Sigma in the pharmaceutical industry.

Eileen Morrissey, the VP of global operational excellence at Merck, has been using the

Six Sigma DMAIC methodology in many areas of the business, from research through distribution. Merck was able to apply the DMAIC methodology to reduce variation in its clinical patient recruitment rates — a transactional and service process. Patient recruitment is a critical variable in how long it takes to complete a clinical trial. By using the structured problem-solving methodology and data analysis, the team was able to identify and eliminate the root causes that impact the variation in the process and reduce the overall cycle time of the trial.

As another example, i3 Research's regulatory affairs department recently began a project to assess whether all of the investigative sites have proper documentation completed to begin participating in a clinical trial. According to Mr. Volpe, more than 75% of the i3 employees' time was focused on following up with the sites on incorrectly completed forms or poor documentation. The Six Sigma team's investigation showed that most of the clinical projects sent research sites a different set of instructions to complete the same FDA form. The team determined the most effective set of instructions and standardized the process across all projects and employees. These improvements focus on simplifying the process for the customer while improving compliance.

"Sometimes what seems simple and obvious has evolved over time as new employees and managers move in and implement their own methods," he says.

The strength of the DMAIC process for continually improving performance is its comprehensive approach. Often represented cyclically, DMAIC helps managers evaluate the insight gained from each step to best understand, analyze, and rectify the problems that exist in a process. Once a process has been controlled, the define phase starts all over again with the next biggest problem.

"Historically without Six Sigma, process improvements also began in a define phase yet quickly moved to an improve phase without gaining a full understanding of the root cause of the problem or the activities that defined the process," Mr. Volpe says. "In many cases, ineffective solutions were crafted to address flawed assessments of the problems or only address their symptoms. Controls were frequently omitted, creating difficulty in monitoring quality as it remained unchanged or slowly returned to an undesirable state."

Because the DMAIC process forces users to follow a structured problem-solving methodology that focuses on fully understanding the process and customer's needs, then uses that data to eliminate defects, it is systematic, focused, and continuous.

A BUSINESS MANAGEMENT SYSTEM

Six Sigma also functions as a business management system, documenting the business processes and customer's requirements, then implementing metrics to monitor performance against those requirements. The data from these metrics help to identify those opportunities for DMAIC projects that will have the most impact on customers, business, and employees.

It is important to include metrics from the customer's perspective, not just the internal business financials.

"I often heard that Jack Welch was told by the General Electric Plastics senior leaders how, on average, their deliveries were on time," Mr. Volpe says. "But Mr. Welch had several friends who were customers, and they were telling him the shipments were either very early or very late. When the early and late deliveries were averaged out, it created the illusion of on-time deliveries. It is important to understand not just the average, but the amount of variation the customer is experiencing."

Operational metrics are very common in the manufacturing world — production per shift, per employee, per machine; cycle time to manufacture a product; setup time to convert a machine; etc. Unfortunately, operational metrics are not as common in the transactional or service processes. A Six Sigma system quickly demonstrates the amount of variation customers and employees experience in a process.

KEYS TO SUCCESSFUL IMPLEMENTATION

"Implementing a Six Sigma quality improvement program is not a magic pill to instantly improve a business's performance, but instead is a structured way to improve the product or service delivered to customers while improving business efficiency," Mr. Volpe says.

He identifies several important factors in implementing a successful quality program:

- Senior-leadership commitment is essential, and the program must be driven from the top down, with execution at all levels. The team must not only commit resources for the project, they must also believe and show enthusiasm in the program.
- Everything is a process; manufacturing vs. service makes no difference. Sometimes the process is simply harder to recognize because a manager can't put his or her hands on the service or follow it through the steps.
- See the business from the customer's perspective. The internal view is usually wrong. Measure processes the way the customer would measure your business, even if you don't like what you see. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Six Sigma's Impact on the Pharmaceutical Industry

Six Sigma will have a dramatic impact on improving the efficiency and quality of the pharmaceutical industry by focusing on improving its processes, especially with continued pressure to reduce the costs of developing new drugs and bringing them to market.

"From my initial perception of the industry, there is a heavy reliance on trying to inspect quality of the processes, which is ineffective and expensive," says Jim Volpe, global director of quality improvement at i3. "Inspection is not the way to eliminate defects; rather processes must be designed to achieve quality from the beginning. A properly designed process can significantly reduce the need to inspect for quality."

In the clinical-trial process, there is a heavy reliance on inspection to assess the accuracy of the data. For example, a paper case report form (CRF) is designed to collect patient information. The investigator records the patient information in his own medical records and then transcribes the information into the CRF. Then a clinical-research associate from the pharmaceutical company visits the investigator's site to assess whether the information is accurately transcribed and collects the CRFs for data entry. The data from the CRF are then entered twice into the database and checked again by various data managers and automated systems. If there is a potential discrepancy, the data are sent back to the investigator for verification once again. In some cases, the data are verified more than five times.

Six Sigma could help solve these types of redundancies while maintaining quality. Although its roots are in manufacturing at Motorola, GE brought Six Sigma to broader pieces of the business world, starting with financial services. Since then, businesses across the spectrum have experienced its benefits, first in manufacturing and then through other transactional services. In the years to come, the possibilities for improvement that Six Sigma can offer for all business aspects of the pharmaceutical industry, and others, will be discovered.