

BIO/PHARMACEUTICAL Outsourcing *Report*

Quality Assurance

Six Sigma Can Give Contractors a Quality Advantage

If you're not improving business, you'll be out of business. That's the mantra quality improvement people espouse, but implementing constant improvement can be difficult, expensive, and time-consuming.

The latest philosophy in total quality management (TQM) is Six Sigma. Started in the 1980s as the in-house quality improvement program for Motorola, the success of Six Sigma there caused the program to spread to additional companies such as General Electric, where its success has become almost legendary. But like other quality efforts, to be successful, Six Sigma demands a serious investment of time, human resources, and sometimes money.

Perhaps because of these demands, the pharmaceutical industry has been slow to sign up for Six Sigma—despite the demonstrated benefits. For example, in a recent informal survey of a dozen leading pharmaceutical companies, only one quality assurance person was aware of a Six Sigma program at his company. It's no wonder sponsors aren't pushing their contractors to adopt it. Six Sigma offers contractors a

way to stand out from their competitors and cement relationships with their sponsors. So why aren't more CROs and CMOs taking an interest in Six Sigma?

The Demands of Six Sigma

It could be sponsors and CROs alike are put off by tackling another quality improvement program. Yet there are differences in Six Sigma that make it stand out from previous quality improvement efforts. Cary Adams is the owner of Adams Associates, a management consulting company that specializes in quality issues. Six Sigma training and consulting comprise a large part of his business.

"Six Sigma is the structured application of tools and techniques of quality management applied on a project basis to achieve strategic business results," Adams says. It serves as an overarching "umbrella" for other quality tools and techniques, bringing their use together under one defining philosophy. Because it's project-based, Six Sigma uses short-term goals to achieve long-term objectives—constant, continuous improvement.

The structure comes from the five phases of Six Sigma: define, measure, analyze, improve, and control. By implementing each of these phases over the course of a project, Six Sigma focuses on tangible improvements. Unlike other quality improvement programs, Six Sigma recognizes that defects will still happen. The goal is to have no more than a few defects per million opportunities. Because Six Sigma allows for a few errors, many TQM experts see it as a realistic approach.

Reduced Costs, Enhanced Revenues

Six Sigma projects are run by "black belts," employees who have been trained on the philosophy and its application. Black belts are backed up by "champions," usually senior management-level employees who have been trained on Six Sigma concepts and have the ability to cut through interdepartmental red tape to ensure black belts get the support they need.

DuPont Pharmaceuticals began training for Six Sigma in fall 1999, with implementation in January 2000. The decision to use Six Sigma wasn't a particularly difficult one. "Six Sigma is a proven process and methodology that has a discipline to attack defects in nearly everything we do in a business. This leads to reduced costs, and in some cases, enhanced revenues. Not many companies shy away from these two things," notes Larry Williamson, a Six Sigma champion at DuPont Pharmaceuticals.

DuPont Pharmaceuticals has chosen to implement Six Sigma throughout the company, with a cross-section of employees selected for training to become champions, black belts, and master black belts. Senior management also received overview training on Six Sigma, according to Williamson.

Although the program has been in place for about a year, the company still considers itself in a learning phase. "This is a new process for us, so it must prove its worth," says Williamson. "Our approach is to create an environment where the program can grow through recognized and sustained positive, bottom-line growth. While we are new at this, we are seeing good progress."

Success depends on the type of commitment an organiza-

tion is willing to make. Some companies are more interested in saying they have black belts than in truly implementing the Six Sigma program. These companies want to achieve General Electric-type quality improvements without doing the same level of work, Adam says. And, though they may see results, their results won't be as dramatic as the results for companies plunging wholeheartedly into Six Sigma.

For companies willing to make the commitment to Six Sigma, training costs vary widely, from \$10,000 per black belt and up. Adams offers web-based training modules for about \$5,000 per person. The self-taught sessions enable participants to go at their own pace, he says. But the costs are more than just financial, according to DuPont Pharmaceuticals.

"Leadership commitment is important, an involved process owner (the ultimate responsible line manager) is important, and continuous learning and support among Six Sigma personnel are important," notes Williamson. "Implementation is not easy, but is worth it." Finally, project selection is key. "You need to set goals to ensure you are striving for the right things that will help the bottom line of your company," he says.

What types of projects lend themselves to Six Sigma? "In the beginning, especially, you want projects to be successful so you can build momentum," according to Rick McDaniel, director of new business development for Stat-A-Matrix, a consulting firm specializing in process improvement. "You really need to limit the scope," he says. The goal is to find projects in which Six Sigma can help the company achieve real cost savings, not just cost avoidance.

Adams agrees, noting that project selection is perhaps the most important indicator of future success. A Six Sigma project needs to have a problem that can be defined in concrete terms, such as cycle time. Such projects also need to be able to return a specific amount to the bottom line. Even a \$150,000 to \$200,000 savings, multiplied by multiple projects, can have a substantial impact on the company bottom line.

"During the first year, we were completing projects while learning," agrees Williamson. "Now that we better understand the process and methodology and have seen the benefits, year two



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should be more targeted and will address problems that are more difficult to resolve.”

“If Six Sigma sounds like a lot of work, it is. But when you look at what the savings are, it’s not hard to justify,” notes McDaniel. “Anywhere you have to

have very high quality, such as the pharmaceutical industry, and that’s combined with high volume, it’s a situation that lends itself to Six Sigma,” he says. Even pharmaceutical companies or CROs that produce relatively few products but have a complex manufacturing process can benefit, adds McDaniel. ♦