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Is Six Sigma Still Relevant for Drugmakers?

By Erik Greb

The global economy is still constraining drugmakers' budgets, and most manufacturers are urgently looking for ways to reduce waste and cut expenses. Several years ago, many pharmaceutical firms were talking about Six Sigma, an industry-neutral organizational change-management strategy that uses statistical tools to improve manufacturing processes. The goal of this strategy is to reduce variation to the point where a process yields fewer than 3.4 defects for every million products. Achieving such a consistent level of quality control could greatly reduce waste and save money for the pharmaceutical industry. But why has talk about Six Sigma died down at a time when it could be of great benefit?

The strategy has generated a backlash, says Jim Catania, managing consultant at Tunnell Consulting. Top managers in the drug industry have noticed news stories about companies, including Home Depot, trying and failing to realize the performance and cost improvements they expected from Six Sigma. Some practitioners who have encountered difficulties have blamed their failures on flaws in the Six Sigma method itself, and these remarks may have created an impression that the strategy doesn't work.

But declaring that Six Sigma doesn't work is akin to declaring that calculus or chemistry doesn't work, says Catania. Failures generally result from poor leadership and execution. Companies need bright people and intelligent application to use the strategy successfully. Unless a firm clearly understands its current baseline performance, its goals for future improvement, and its strategy for achieving these goals, its Six Sigma program will not be optimized, says Catania.

Six Sigma is most appropriate for supplies or processes over which a company has tight control, and it might not be suitable for every aspect of pharmaceutical manufacturing, says Chris Moreton, vice-president of pharmaceutical sciences at Finnbrit Consulting and a member of *Pharmaceutical Technology's* Editorial Advisory Board. For example, a raw material's median particle size can vary by as much as $\pm 20\%$, partly because the industry does not have sufficient understanding or control of some common unit processes (e.g., milling) that determine physical properties. This amount of variability is "not good enough for Six Sigma unless you've got a tremendously robust process," says Moreton.

Imposing the Six Sigma strategy on established formulations and products is not straightforward, and may not work. A better approach is to begin with a quality-by-design (QbD) program for a new product that is targeted to Six Sigma. A drugmaker must understand and be able to control its design space to achieve Six Sigma, says Moreton. QbD, "the ultimate control strategy," is the basis for Six Sigma, and personnel can monitor the process and maintain control using process analytical technologies, he adds.


Training employees in the statistical tools that make up Six Sigma is only one small facet in implementing the

method, as some companies have learned. “We have seen people train black belts without really focusing them” and embedding them in the process, says Catania. When black belts “drop in like Special Forces and try to effect change remotely,” they will not be effective, he adds.

Instead, the Six Sigma strategy must become part of day-to-day operations for a company to attain all of its benefits. “We’ve embedded it into our workforce and how we handle projects, whether it’s a new customer coming in, process improvement on the line, or even investigations in what we’re doing,” says David Pittman, director of technical operations, inspection, packaging, and warehouse for OsoBio.

By providing a framework for organizational change management, the Six Sigma strategy “creates the discipline and path to ensure that changes are data driven, that the stakeholders are enrolled, that the implementation has a baseline measurement, and that improvement is real and sustainable,” says Catania. When the methodology is “applied with rigor and discipline, it absolutely works.” Pharmaceutical heavyweights such as Johnson and Johnson, Merck, and Genentech all have active Six Sigma initiatives, notes Catania. The current economy might provide a further reason for more companies to embrace this strategy for process improvement.



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