

Getting it Right First Time: Six Sigma for Continuous and Breakthrough Improvement

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300
200
100



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As a set of state-of-the-art tools for solving operations problems, Six Sigma can be used for both continuous or breakthrough improvement. What separates the two is the structure by which they are managed. When managers confuse the two, it usually results in a below par performance. Worse still, it could result in another dead-end quality programme. This article will present guidelines for managing continuous and breakthrough improvements in the pharmaceutical industry with examples of Six Sigma applied to each.

CONTINUOUS AND BREAKTHROUGH IMPROVEMENT

Continuous improvement (CI) is about many small improvements initiated and implemented by all members of an organisation in order to improve the quality of their working processes and practices. Simplifying administrative processes by eliminating unnecessary copies, racks for organising equipment in a more visual and orderly fashion, and colour coding dossiers in a laboratory for easy identification are all examples of CI. Thus, it both reflects and creates a culture of quality.

Breakthrough improvement (BI) involves major improvements in key business areas. They are often chronic problems solved permanently through focused, dedicated resources working for a limited period of time. Due to the investments in time and attention required, BI projects are selected by a management team who typically act as a steering group. The improvement goal is between 50 and 95 per cent improvement in four to 12 months, depending on the scope of the project. Usually the scope of inquiry crosses multiple functional boundaries. These are wonderful opportunities for developing next generation leaders – an

equally important aspect of creating an enduring quality culture. BI projects yield the highest economic return in the short- to medium-term.

In Six Sigma parlance, CI is carried out by Yellow and White Belts who are trained in the basic DMAIC approach and tools. Black Belts are involved in breakthrough improvements. Depending on the project, Green Belts could be involved in both types of improvement. Design for Six Sigma projects are typically aiming for breakthroughs in performance.

Figure 1: Two Management Approaches

	Continuous	Breakthrough
Most Important Objective	Broad people involvement in improvement process	Major improvements in key business areas through people involvement
Magnitude of Improvement	10%-50%	50%-95%
Project Selection and Goal Setting	Team (within guidelines)	Senior Management or Steering Committee

For 15 years, a pharmaceutical manufacturer experienced variations in a production process that resulted in periodic batch failures. Everyone in the company had their own theories about the reasons why: the chemistry of particle sizes, humidity (depending on the time of the year), equipment settings and so on. In nine months, a cross-functional team led by a quality manager cracked the code.

What follows are examples of both Six Sigma continuous and breakthrough improvements from a medium-sized European pharmaceutical company.

CONTINUOUS IMPROVEMENT FOR REDUCING PACKAGING EQUIPMENT DOWNTIME

A European pharmaceutical company began a restructuring process that included an investment of €20 million to create a lean operations factory. After coping with the teething problems of starting up the new plant, the plant manager was confronted with yet another challenge: the mind-sets in the organisation had not evolved with the changes. This was reflected in the fact that, while raw materials and products could flow continuously from the granulation to the packaging of finished products, supervisors and operators followed old practices in running the equipment and managing their time within departments.

Six Sigma was chosen as the continuous improvement methodology to identify and solve the problems relating to continuous flow production. The first step was to coach packaging supervisors and operators in the application of the Six Sigma method, thereby providing them with the tools to quantify the downtime problem, identify root causes, and develop and implement solutions. The initiative started with a three-day project team training. It was designed to give participants an overview of Six Sigma, further refine the scope of their project and build cohesion among a group of people that were not accustomed to working in project teams. At first, there was resistance to the whole idea of measuring, as operators saw it as a camouflaged step towards reducing their work freedom. However, what seemed to open their minds were the benefits and insight gained by taking part in the Six Sigma teams. The operators identified several potential root causes and succeeded in building a measurement system to document cause/effect relationships. By fixing chronic issues that irritated the operators, maintenance engineering staff won the credibility of the operators. This indicated to them that management were serious about improvement.

Over a period of nine months, the company reduced unplanned downtime in packaging by identifying several critical problems: dust, lack of co-operation between packaging lines, incorrect machine calibration and lack of proactive maintenance. This situation called for a new common working culture: measuring,

analysing and taking action to reduce downtime became part of an everyday practice.

All in all, the most durable benefit was the skills learned in teamwork and leadership. The team succeeded not only in implementing proactive procedures for machine maintenance, but also by creating closer co-operation between technicians, operators and packaging lines. This increased operator responsibility and empowerment toward preventative maintenance – all improvements that control measures have validated as durable.

CHRONIC YIELD PROBLEM SOLVED USING SIX SIGMA

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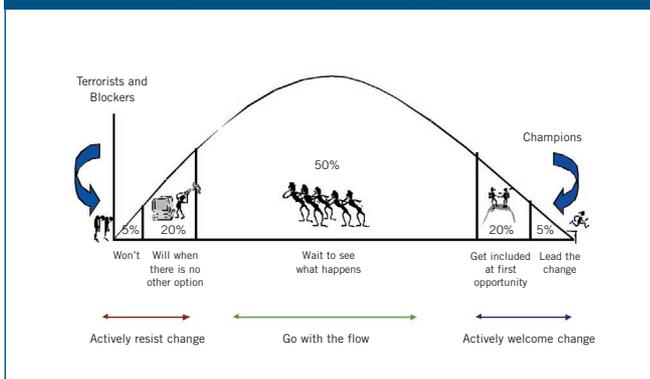
The company used Six Sigma for breakthrough improvement in order to solve this chronic production problem. A group consisting of a quality manager, a cross-function team of operators, laboratory technicians, and process engineers started out by relabelling every pet theory as a hypothesis and tested them against data. As it turned out, several favourite theories failed to stand up to the scrutiny of fact-based analysis.

The process led to interesting results, the breakthrough coming from the collective knowledge of the cross-functional

Figure 2: Two Management Approaches

	Continuous	Breakthrough
Team Focus	Function (part of a process)	Process or Product
Team Make-up	Natural work group	Cross-functional
Team Size	8-12 members	5-7 members
How Many	Unlimited	Few, most important
How Long	Year after year	4 to 12 months
Type of Activity	Ongoing, day-to-day	Special, temporary

Figure 3: Reaching the Tipping Point



team. Upon closer inspection of the data on lost batches, the operators remarked that problems in content uniformity occurred at the same time as agglomerates in the base material. Also, they found that the agglomerates had more of the expected amounts of flavour additive. Finally, the teams concluded that the process of mixing flavour additives was one of the root causes for lumps, resulting in too little vitamin D3 in some tablets. This gave the team a chance to develop and implement simple procedural changes for mixing in flavour additives. Control measures are now in place to monitor other critical variables. Furthermore, this pointed to the need for a future project variation reduction project further upstream. Now, more than ever before, there are frequent and fact-based discussions between functions and levels in the organisation, working together so as to improve production yields.

The company succeeded in reducing batch failures from a yearly average of 12 to two and are on their way to eliminating them entirely. By approaching the problems with fact-based analytical tools, they improved the production process to such an extent that the company generated net-savings of nearly €500,000 per year. As they managed to improve the uniformity of content, they set off a positive chain reaction effecting downstream operations: tablet compression and packaging.

CONCLUSION

Quick gains through continuous improvement are an excellent way to engage change champions to demonstrate that Six Sigma can improve the daily working lives of employees. It helps reach the magic tipping point of 20 per cent of the population who will convince the 'wait and see' crowd that Six Sigma is worthwhile. Simultaneously, well-chosen breakthrough improvements deliver capabilities that can change the economics and strategic capabilities of a business. Leaders who appreciate the nuances of managing both through different approaches, yet under the same Six Sigma improvement initiative, will have their cake and eat it too – enduring culture change that has the potential of a 400 per cent return on investment! ♦

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