Improving **quality** in pharma manufacturing

For pharmaceutical and medical-product companies, adopting world-class manufacturing processes can create a competitive advantage by reducing regulatory risk and production costs.

Anil G. D’souza, David J. Keeling, and Richard D. Phillips

**Article at a glance**

Drug and medical-product manufacturers tend to trail companies in other industries in measuring and controlling product quality. The result: inefficient processes and huge regulatory fines.

Many pharma executives hesitate to change their approach to quality management, claiming that strict regulation makes changes far too costly and complicated. But even in the tightest regulatory markets, a few pharma companies have managed to raise quality significantly and to reduce regulatory risk.

The ways these leaders have raised quality and lowered compliance risk include a cultural shift toward manufacturing quality, adding quality measures midstream to manufacturing processes, and simplifying quality- and compliance-management systems.
The world’s leading manufacturers—including producers of semiconductors and of goods for the automotive, aerospace, and electronics industries—constantly refine their processes for measuring and controlling product quality. In pharmaceuticals and medical products, however, quality control has historically taken a backseat to innovative science and compelling marketing, the standard drivers of the industry’s profitability. Recently, though, industry executives have had no choice but to sit up and take notice, as poor quality and related compliance issues have cost the industry more than $700 million in fines since 2001 and billions more in lost revenues. Addressing compliance matters eats up big chunks of management’s time and attention and, in some cases, has led to increases of more than 20 percent in the cost of goods sold.

While some pharma companies are improving their manufacturing quality substantially, many more have been slow to study and achieve world-class practices. They may not feel the imperative for change until a major compliance issue occurs. Rather than building quality into and across manufacturing processes themselves, many companies have used the risky and costly method of trying to ensure quality by removing defective products during inspections. This approach is not sustainable, especially as the Food and Drug Administration (FDA)—the US government’s main oversight body for the industry—and other regulatory agencies have shifted their focus to monitor not only a company’s outputs but also its processes and systems.

In the face of a challenging regulatory environment, some leading pharmaceutical and medical-product companies have found ways to improve quality and costs significantly. To drive this kind of beneficial change, companies must first create a culture where quality objectives are transparent, well understood, and undoubtedly important. Then managers must focus resources on the product and process attributes truly critical to delivering quality products. Adding quality measures to manufacturing processes midstream, simplifying quality and compliance-management systems, and working to monitor and measure quality performance effectively will combine to raise quality and lower the risk of compliance issues. Companies that succeed in implementing these changes can create a competitive advantage through superior performance on cost and quality: they dramatically reduce variability, the risk of noncompliance, and time to market while freeing up funds for investment.

**What pharma companies should change**

As the pharmaceutical sector has grown—revenues in the United States are three times greater than they were a decade ago, while those in Western Europe have doubled during that time—regulators around the world have become more sophisticated in ensuring that drugs are safe and effective. As late as the 1980s, for
instance, the primary focus of the FDA was to prevent fraudulent drugs from reaching consumers. By the late 1990s it focused more on the drugmakers’ processes. Today the FDA has taken a much more systemwide approach to evaluating the quality of pharmaceutical manufacturing plants and networks.

But some pharma companies haven’t adapted well. Many continue to focus mainly on near-term regulatory inspections and have been spending increasing amounts of money to fix problems only after they arise. The common pitfalls of this approach include gaps in identifying important sources of variability, insufficient and ineffective testing during production, and a failure to resolve quality issues in a timely manner. Such flaws can add up to big problems—and big fines.

New processes that help pharma companies keep up with best practices in manufacturing can significantly reduce compliance risk at low cost. Although a small team of managers must focus on driving change, large investments in people or equipment typically are not required to transform a company’s quality culture and performance.

CEOs, heads of operations, heads of quality, and other senior managers play an important role in promoting such changes. They must clearly and visibly commit themselves to understanding employee mind-sets around quality and to changing the attitudes and behavior of everyone from other senior leaders down to line operators. In addition to creating a culture where quality comes first, operational leaders must learn which product attributes matter most for the caliber of the final product, enhance manufacturing and quality processes, and better allocate resources devoted to quality.

Create a culture where quality matters

Leading pharma companies gather insights on their current quality culture through interviews, surveys, and focus groups. At one company, such an effort found that accountability for quality performance wasn’t at all clear to its employees. Senior leaders didn’t stress the importance of quality through their own behavior, and key employees lacked the capabilities—from technical expertise to communication skills—needed to manufacture high-quality products. Armed with these insights, the company developed a plan to fill in the capability gaps.

The resulting changes to the organization and employees’ behavior led to a rapid and measurable shift in the company’s approach to improving quality. Within about a year, people across all levels could articulate quality objectives and aspirations, and a new sense of empowerment emerged around the ability and responsibility of employees to raise and address potential risks.

- Senior leaders learned key cultural messages and now continually
reinforce them through corporate communications, staff meetings, and site visits. Whenever the CEO discusses operational objectives, for instance, he says that one of the ultimate goals is to achieve industry-leading performance on critical quality metrics. Other senior managers are advised to ask plant managers and staff questions about quality at every visit.

- Plant supervisors are trained to model and coach the desired behavior in order to improve productivity and manufacturing quality. They walk the floor on a regular basis, calling attention to quality targets posted at the end of lines and making sure that targets are set and that managers address such issues. Those managers send a strong message when they ask about quality performance on every possible occasion.

- Frontline workers are meaningfully and regularly engaged in improving the company’s quality performance. After all, corporate leaders and even senior engineers don’t necessarily know when a particular machine is the root of a serious quality problem. To get workers to contribute, the company first ensured that they had the right technical expertise. Operators received additional training on how to monitor variability in production processes. Team leaders and supervisors have the authority and confidence to stop production lines for recurring problems and to put together the right teams to fix them. In addition, quality performance is a part of individual and team performance reviews, and the company publicly rewards employees who receive top scores for their efforts.

The tasks involved in achieving such a cultural transformation, while often straightforward, are critically important, and most pharma companies simply aren’t undertaking them. Creating a corporate culture where every employee understands the importance of and takes responsibility for quality propels all the components of an improvement initiative.

**Create a more efficient and effective quality system**

Beyond sweeping cultural change, the next step toward manufacturing high-quality products—and achieving regulatory compliance—is identifying the handful of factors that really affect quality. Many pharma companies haven’t taken the time to map out the specific product attributes and processes that truly matter. In one case, we saw a company spend as much time perfecting a drug’s color as it did ensuring the drug was effective and had an adequate shelf life.

In our experience, it’s not complicated to identify and rank key quality attributes of
most products. To determine which ones are most important, operations managers can tap internal sources, including the sales, marketing, product-development, and technical staff. External sources, such as physicians or customers, can also contribute invaluable insights, particularly on ranking customer needs, which can vary from product to product. Taste isn’t highly valued for painkillers, for example, but for children’s cough syrup, it might be quite important. Many companies don’t spend sufficient time on this step. Instead, they devote inordinate amounts of time to complex internal processes and extensive, often redundant, authorization processes to support noncritical activities.

Once pharma companies identify the product attributes that most affect quality, they can work to align their efforts with those attributes. To achieve consistency on the most critical ones, an ideal quality and compliance system should properly allocate resources. But many pharmaceutical companies have overly complex systems. Since these companies have not identified the few factors for each production line that are critical to the quality of the end products, they often test and retest too late in the process. Many of these screenings have limited value and result in missed opportunities to identify and isolate variability upstream.

A streamlined quality system makes it easier to find and remove wasteful activities in quality processes. One pharma company significantly raised its efficiency when it simplified the complex physical layout of its manufacturing facility and encouraged workers not to leave unmarked tools and supplies lying about. Before the change, the lab staff spent 60 percent of its time walking around, moving supplies and tools from one workstation to another, talking, or waiting—and adding no value. After the company applied best practices, it cut that time by 50 percent.

Another way for pharma companies to make their quality systems more efficient is to work harder at building quality measures into the manufacturing processes themselves. Rather than inspecting finished products, and therefore failing to generate insights into the causes of defects, world-class manufacturers monitor the performance of production lines and predict the variability that may result in defective products. As we noted, changing employee mind-sets and the organization’s culture can spur successful changes of this nature. These efforts translate into hands-on, practical improvements in day-to-day work.

We observed one example of such a change at a medical-product maker whose line workers frequently identified defective products at various points and immediately took them offline without halting production. The workers would then fix the defects and reintroduce the goods into the production line without trying to determine why a defect had occurred or working to prevent it from occurring again. After they discontinued this practice, the company uncovered and addressed important problems and improvement opportunities.
First, executives discovered what frontline employees had apparently known for a long time—that because defective products had been taken offline, repaired, and put back online, an artificially high number—90 percent or more—passed the first inspection, when in reality only 30 to 50 percent should have been approved. For one product line, managers learned that they should aspire to a true first-pass inspection acceptance rate (the percentage of products that meet specifications without any rework) of at least 95 percent. Then the company documented the reasons so many products would have failed the initial quality inspection. Armed with this knowledge, the company improved the manufacturing process, significantly lowered the risks related to poor quality, and focused on the attributes critical to quality.

It took more than 18 months to implement the design changes fully, but a few process fixes yielded almost immediate results. Within just 6 months the manufacturer doubled the first-inspection acceptance rates of several product lines. As a result quality is now embedded in the manufacturing process, and cycle times are 20 percent shorter.

Manage—and measure—quality performance

A push to make quality central to a company’s culture should increase transparency around such issues throughout the organization, both before and after problems occur. One common mistake can inhibit this kind of progress: using large numbers of metrics—up to 50, at both the plant and corporate level—often without consistent definitions. When choosing performance metrics, operations leaders should concentrate on tracking the few that matter, such as first-pass yields, internal quality observations, or quality cycle times, to help plant managers understand what drives better performance.

Knowing the first-pass yields of a particular manufacturing line, for example, can be critical. Yet this same metric may be meaningless when aggregated at the corporate level across different products, lines, and plants. Similarly, the number of FDA penalties imposed on a company may give senior corporate employees an indication of its overall regulatory performance but is not actionable for any one plant.

In our experience, many pharma companies can apply techniques from other industries to improve quality performance. Simple tools placed along the production line—such as whiteboards with important line-level metrics, as well as depictions of what defective devices, tablets, or other products actually look like—are vital to increasing transparency and promoting constant improvement.

It’s critical for the shop floor to make and “own” process changes, but as with any major change-management effort, sustained improvements in manufacturing
quality ultimately depend on the commitment of leadership. For pharma companies, this commitment can’t be limited to the executive specifically responsible for quality; all leaders must work to create a culture where quality products are a top priority. Such turnarounds require a relentless focus on the most important drivers of quality, a determined effort to build quality into manufacturing processes, and a commitment from the leadership to align management processes with this goal. Pharma companies that move too slowly to address this challenge risk much higher costs and much more trouble from regulators.

Indeed, a significant benefit of a greater emphasis on quality is a better relationship with regulators. Although a spirit of collaboration cannot be achieved overnight, it can lead drugmakers and regulators to share information and insights. Such a shift from a purely transactional, audit-based dialogue to a more productive, collaborative one can help companies shape manufacturing processes more efficiently and further improve quality.

1 Although this article focuses on manufacturing, it’s important to acknowledge that the product-development staff must first build quality into the original product design, which is a major driver of quality downstream.

Related Articles on www.mckinseyquarterly.com

“Pharma leaps offshore”

“The changing role of IT in pharma”

“Beyond manufacturing: the evolution of lean production”

Copyright © 2007 McKinsey & Company. All rights reserved.