



Executives & Improvement

10 things pharma executives need to know about improvement

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THE FAMILIAR METAPHORS FOR BUSINESS competition — war, sports, chess — suggest that the leader's job is to lead the company to victory. But in the real world of business, the game never ends; the goal posts constantly recede, and ultimate triumph never arrives. You can never win, only improve. The real job of the leader — especially the pharmaceutical company leader faced with continuing globalization, relentless competition, and increasing cost pressures — is not to show the way to victory but to show the way to improvement — again and again — and whatever temporary advantage it confers in a world of endless competition. As a result, most pharmaceutical executives today have two jobs: doing their work to serve their customers and improving how that work gets done (see *Improving vs. Doing* on the next page).

The two jobs differ sharply. When we are doing our work, we are operating within the processes — business, manufacturing, operational or administrative — through which most work gets done. But trying to improve those processes requires that we step outside of them, analyze them and devise better ways of doing them. The big problem organizations struggle with is how to allocate time and resources to ensure that both jobs get done.

Yet, despite the fact that the ability to lead improvement is critically important to a company's long-term success and an executive's career, few companies make leading improvement a part of leadership development programs or a condition of promotion. Further, given the bewildering variety of improvement methodologies available — Six Sigma, Lean, Baldrige Assessment, ISO 9000, and more — it's not surprising that many executives report that they hardly know where to start. But start they should, because these improvement methodolo-

gies are beginning to coalesce into a comprehensive, 21st century approach to quality.

To help executives orient themselves in this new world without drowning in the technical details, this article will present 10 basic principles of improvement that savvy pharmaceutical companies and ambitious executives need to know in order to thrive in the never-ending races of competition and career.

The Improvement Imperative

In 2003 a former Deputy Director at the Office of Pharmaceutical Science CDER/FDA told the *Wall Street Journal*, "The pharmaceutical industry has a little secret: even as it invents futuristic new drugs, its manufacturing techniques lay far behind those of potato chips and laundry-soap makers." In the intervening years, the imperative to improve antiquated and costly manufacturing processes has only grown more pressing. According to various estimates and the annual reports of top pharmaceutical companies, manufacturing costs eat up approximately 25% of revenues, far more than R&D, which consumes up to approximately 20%. At the same time, big pharma, facing major patent expirations and thin pipelines, is finding that the old blockbuster business model is breaking down ("The Dangers of Swinging for the Fences," Joe Nocera, *New York Times*, January 27, 2007). Overly complex and wasteful processes and systems used to produce blockbuster drugs

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Improving vs. Doing

Organizations today need people who can both manage and lead. In many organizations the percentage of time spent on each activity, according to role, follows this general pattern:

Role	Leading/ "Improving" Work	Managing/ "Doing" Work
Executives	90%	10%
Managers	70%	30%
Others	30%	70%

with \$1 billion in annual sales cannot efficiently produce drugs with \$500 million in annual sales. Only by improving and redesigning processes of all types — manufacturing, R&D, marketing, sales — can pharma companies generate bottom-line savings that can be used to fuel growth and speed up the development of new products to create top-line growth.

The push for improvement is also coming from FDA, EMEA, and ICH guidelines that encourage scientifically-based approaches to quality and compliance that promise to usher in a new era in manufacturing. However, implementing the concepts embodied in those guidelines — Process Analytical Technology (PAT), Quality by Design (QbD), and Design Space — will require new, more rigorous ways of doing things.

Given a future in which the big winners in pharma are likely to be low-cost producers and companies that innovate, the potential benefits of fulfilling the improvement imperative are significant. In manufacturing, reduced rework and fewer lost batches mean improved yields and higher productivity. Additional benefits include more compliant processes, fewer inspections and costly shutdowns, reduced regulatory burden, increased equipment uptime and plant utilization, more robust products, processes, and analytical methods, and greater speed to market with more innovative products. In non-manufacturing processes, the benefits include better quality of service, shorter cycle times, less rework and waste, reduced cost and streamlined processes.

Such improvement can be a profitable business. For large companies, comprehensive improvement programs typically return 1-2% of sales yearly to the bottom line. For small and medium companies, the return is 3-4% of sales yearly. Further, the savings accumulate year over year: 2% per year becomes 4% in Year 2, 6% in Year 3, and so on.

Realizing those returns begins with an understanding of principles of improvement that are straightforward, in many ways common-sensical, and easily put to work by executives who want to make a real difference.

1. Adopt a holistic approach

Six Sigma, Lean, TQM, and numerous other improvement approaches have their partisans, powerful techniques, and success stories. Proponents of Six Sigma may insist that reducing process variation is the key to improved performance. Adherents of Lean may say that reducing waste is the key; why reduce variation in an inherently wasteful process? Many users of TQM focus on the importance of teamwork.

How to choose among these competing claims to superiority? The short answer is: don't. Improvement is too important to

be confined to the tools of a single methodology. Meeting the overwhelming imperative to improve requires a holistic performance improvement methodology that applies to improvement opportunities of all kinds. Such a comprehensive approach enables you to apply to a particular problem the tools that are most appropriate — no matter where they originate — in a structured and sequenced approach.

Different stages of improvement call for different tools. In the early stages you need tools for correcting obvious problems with a process, fixing inadequate measurement systems, and ensuring the consistency of process inputs, whether raw materials in manufacturing or data in non-manufacturing processes. Complexity, waste, and non-value-added work should also be reduced to increase efficiency. Later stages of improvement focus on optimizing and controlling processes by improving value-added work steps, shifting the process average and reducing variation around it, improving process flow, and reducing cycle time. Process problems in pharmaceuticals are usually multi-dimensional, requiring a variety of methodologies for their solution. Only a holistic methodology can provide all of the tools to address all of these stages and dimensions.

A genuinely holistic approach works in all areas, functions, and processes of the business — from R&D to manufacturing to finance to marketing, to quality assurance, and more. It works in all cultures, providing a common language of improvement and a common tool set, characteristics that are critical for today's global pharmaceutical company. It should also be able to address all measures of performance — quality, cost, delivery and customer satisfaction, as well all aspects of process management, including process design/redesign, improvement, and control. It should help develop a culture of continuous improvement.

2. Acquire a reasonable understanding of the tools

From Frederick W. Taylor's time-and-motion studies to the latest in statistically sophisticated decision-support methodologies, we've learned a lot about improvement (see *A Brief History of Improvement Approaches* on the next page). It's not necessary, however, for executives to become professional statisticians or even highly schooled in improvement tools. In most cases, leaders will not be the ones directly applying the tools - their chief responsibility will be deploying and overseeing the improvement system. But they should acquire an understanding of what the tools are, when they should be applied, and what information each produces. Otherwise, they will be unable to conduct meaningful project reviews.

3. Involve top management

Whether you are part of top management initiating improvement or a mid-level executive proposing an improvement initiative to superiors, you should understand that without the full support and involvement of top management the improvement effort is likely to wither on the vine. That doesn't mean mere cheerleading or statements of support through E-mail, newsletters, and the like. It means creating a real sense of urgency about the need to improve and doing things that increase the likelihood of success: removing obstacles, allocating financial and human resources to the effort, regularly reviewing its progress, and ensuring recognition and rewards for participants. In comprehensive, high-level improvement programs designed to radically change the

A Brief History of Improvement Approaches

- Scientific Management (Taylor, Turn of 20th century)
- Statistical Quality Control (1920s-40s)
- Quality Circles (1950s-60s)
- Statistical Process Control (1960s-70s)
- Deming, Juran and Crosby (1980s-90s)
- Total Quality Management (1980s-90s)
- ISO 9000 (1980s)
- Reengineering (1990s)
- Six Sigma (1990s)
- Lean (2000)
- Lean Six Sigma (present)

organization's way of working, senior leaders should directly oversee implementation.

4. Focus on improvement, not on training

Many companies shy away from large-scale improvement programs because they don't want to make large investments in training employees in unfamiliar improvement methods. Further, there is often a long lag time between the end of training and the emergence of concrete results from subsequent improvement projects. Mid-level executives especially are sometimes reluctant to propose and push improvement programs with such high training costs and deferred payback.

There is, however, an elegant solution to the problem: combine training with real improvement projects, not academic exercises. Project-based training offers a number of advantages. First, it produces immediate financial and business results that, in effect, pay for the training right away. Second, participants take real-world projects far more seriously than empty exercises and devote their best energies to the effort. Third, by linking training projects to business priorities, training is transformed into improvement. With a clear, measurable business benefit as the goal of every training event, a doubly compelling business case can be made on the basis of the benefits from the improvements themselves and on the basis of the cost-effective approach to training.

5. Use top talent to conduct improvement initiatives

If improvement is truly important to your company's success, the effort will be entrusted to your most talented people. In fact, improvement and changing how work gets done is too difficult a problem to be left to anyone but your most capable people. Assigning top talent to improvement initiatives also sends the unmistakable message to everyone in the organization that leadership regards it as an important priority. Further, most people are savvy enough to recognize whether really talented people have been delegated or merely people who are deemed expendable on other projects. If it's the latter, other personnel can justifiably conclude that they need not take the improvement program seriously.

6. Build the supporting infrastructure

Faced with the imperative to improve continuously, it is short-sighted to regard improvement initiatives as ad hoc undertakings in need of no permanent infrastructure to support and execute them efficiently and repeatedly. The requisite infrastructure includes four elements:

A structured approach to problem-solving: This could be, for example, Six Sigma's DMAIC (define, measure, analyze, improve, control) for improving existing processes and Design for Six Sigma for generating and designing new processes — generalized of course for a holistic improvement framework.

Proven analytical techniques: To better understand, trouble-shoot, and improve manufacturing and non-manufacturing processes alike, your analytical techniques should be both qualitative and quantitative. Qualitative techniques include interviewing, expert opinion, brainstorming, hypothesis-generation, process and value stream mapping and cause and effect matrix. Useful quantitative techniques include Pareto charting, control chart analysis, regression modeling, multivariate studies and design of experiments (DoE), to name only a few.

Personnel skilled in improvement: These are the leaders through whom projects are realized. As they become increasingly skilled in leading improvement and training colleagues, they form a permanent cadre of improvement experts who can be relied upon to deliver superior improvement efficiently and expertly.

Management systems: To realize the potential synergies of differing projects and to keep the organization tightly focused on its overriding strategic objectives, you should create an overall improvement system that guides and integrates all types of organizational improvement and creates the supporting management systems required to sustain it. It isn't necessary to create new management systems but to integrate improvement management systems with existing management systems. Improvement management systems include communications, project selection, project portfolio management, measurement, and recognition and reward systems. The measurement system is the most frequently overlooked such system — and one of the most important. In the absence of an adequate and appropriate measurement system, it's virtually impossible to improve the performance of a manufacturing or a business process, increase customer satisfaction, or ensure the quality of a product or service.

With these four elements in place, you can begin to establish an enterprise-wide culture of continuous improvement.

7. Select the right projects

Few components of improvement programs are as critical as selection of the right projects. The project selection process identifies the right improvement approach and thereby identifies the right personnel and tools to be used. There are a number of criteria for identifying the right projects (see *Selecting the Right Improvement Projects*) but above all, you should pursue projects that produce the highest value in relation to business goals. This means that before beginning a project, you should know what it's worth to the bottom line. This makes the Finance department an active participant in the improvement program, a role that is new for Finance in most organizations but one that is critical for the project selection process.

A top-down approach to project selection employs business

Selecting the Right Improvement Projects

A proposed improvement project is worth pursuing if it:

- Clearly connects to business priorities, including strategic and annual operating plans
- Addresses a problem of major importance to the organization and produces significant (e.g. >50%) improvements in process performance and financial benefits (e.g. >\$250,000 per year)
- Encompasses a reasonable scope and is doable in three to six months
- Offers clear quantitative measures of success
- Enjoys support and approval of management

goals to generate projects, while the bottom-up approach addresses performance gaps that arise from within the operations of the organization and the improvement of which can be justified financially. In both cases, projects should be doable in three to six months. Organizations typically lose interest in projects running longer than six months — people get transferred to other jobs, priorities change, deferred results sap motivation. To avoid these pitfalls, projects lasting eight to 12 months or longer can be divided into sub-projects of shorter duration and then conducted sequentially or in parallel.

8. Develop process and systems understanding

Processes and systems don't get better by themselves. In fact, in line with the principle of entropy embodied in the second law of thermodynamics, they inevitably deteriorate if left alone. Further, you cannot improve or control a process you don't understand or the larger systems that processes create. You understand a process when:

- Critical variables that drive the process are known.
- Critical uncontrolled variables that affect the process output are known.
- The process has been designed to be insensitive to these uncontrolled variations.
- Measurement systems are in place and the amount of measurement variation is known.
- Process capability is known.
- Effective process control procedures and control plans are in place.
- The performance of the process over time can be reliably predicted.

Again, it is not necessary for executives to know how to apply the sophisticated statistical methods used to achieve process and systems understanding. They need only appreciate its importance and make sure that the resources are in place to pursue it with the requisite rigor.

9. Plan for sustaining the improvements at the beginning of the initiative

Many organizations focus on sustaining the gains only after improvement has been achieved. That's backwards. You should begin to focus on sustaining improvement gains before an improvement project begins and during the first six months of its implementation — that is, at the strategic and tactical levels, respectively. Otherwise, improvements are unlikely to last.

10. Use improvement for leadership development

Although the ability to help the organization move from one way of working to another is a key leadership skill today, it has been largely missing from most companies' leadership development programs. Further, it is up to leaders to instill a culture of continuous improvement. If such a culture is to really take root, then the improvement system and improvement projects should be an integral part of leadership development. Although Jack Welch, retired chief executive officer of GE, was speaking of Six Sigma, he could have been talking about any effective improvement system when he said, "perhaps the biggest but most unheralded benefit . . . is its capacity to develop a cadre of great leaders." As he recognized, tools don't make improvements. Leaders do. ■



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