Standard Operating Procedures: They may be Standard. But are they Effective?

The Opportunities and Pitfalls of Standard Operating Procedures

Just because an operating procedure is "Standard" doesn't mean that it's the one you should adhere to. This is especially true in the area of quality and compliance. There is a fundamental difference between compliance, which is compulsory, and quality which is a choice. Standard Operating Procedures (SOPs), simply put, define the essential steps, their sequence, and the precautions necessary to formally repeat a quality performance. What does that mean? SOPs are a blueprint for risk mitigation.

SOPs may specify how a company should control variations and ensure predictability, but this is no guarantee. And while Good Manufacturing Practices (GMPs) may be used to identify the problem; they don't describe a way to improve quality. Again, it is a choice. Industries have to improve control of their own processes with the focus not simply on compliance.

Why? Because compliance merely demonstrates and documents adherence to a requirement. It deals with the symptoms of a problem. Quality proactively deals with the problem itself.

SOPs: Why Status Quo is the Enemy of Progress

Restructuring SOPs can seem complicated and expensive, but it is nothing compared to the time and money required to solve devastating compliance problems and waiting out shutdowns. Investments in quality may feel "compulsory due to compliance" or require complicated change control efforts, but that does not take into account the risks and also undervalues the business impact. The costs of non-compliance, as well as the opportunity costs of not optimizing operational processes, are real. And the total cost of remediation is far greater than organizations realize.

The analogy here is a familiar one, but precisely on point: Don't fight fires. Prevent them. The public holds as heroes the firefighter that carries a baby out of a burning building. But more important to everyone is the person who changes the batteries in the building's smoke alarms or promotes effective fire proofing procedures.

SOPs: Affecting Your Bottom Line

SOPs can be complex—both to create and to maintain. But the United States Food and Drug Administration (FDA) has become more diligent and more intensive in its inspections over the last two decades.

Since 2009, the FDA has made enforcement and compliance operations a Top Priority. Over the last four years, FDA leadership has actively worked to strengthen the Agency's enforcement policies—as a result, FDA enforcement activities have increased steadily.

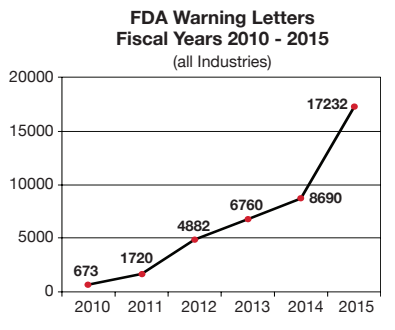
The FDA has also implemented multiple new enforcement policies, including a more efficient review of warning letters, increased misdemeanor prosecutions, created the "Bad Ad" program, and increased the role and responsibility of FDA enforcement officials. Regulatory and procedural changes have redirected the course of the FDA's enforcement functions and will have long-lasting effects on regulated industry.

Therefore, cost-cutting or lack of investment in quality control are recipes for disaster. And as the levels of complexity in the process have risen, so have the number of quality incidents—faster than the rate of growth in the industry. It has been shown that 25% of FDA 483 Warning Letters involved Management Oversight (or lack thereof) as the leading reason.[1]

Between December 2010 and January 1, 2013 (26 months), the FDA issued 1,600 warning letters. The number of Pharma companies that have received FDA Warning Letters, or that are under consent decrees, clearly indicates that compliance complexity is a significant problem in the industry. The impact of these warning letters can be considerable. They not only affect a company's bottom line with unprecedented financial impact, but they can also affect companies in other ways. In fact, a study has shown that these warnings can cause:[2]

- Reputation Damage
- Loss of Business
- Loss of Stockholder Confidence

There have been dramatic increases in the number of incidents reported by the FDA, as well as the severity of those incidents. Quality Management System (QMS) standards have not kept pace with a growing variety of products and technological complexity. There is a competing mindset that compliance is difficult and costly—but not nearly as costly as disregarding these issues.



of all **FDA recalls** are **CDRH related**

of **drug shortages** resulted from **quality concerns** while **relying on incorrect SOPs**

While SOPs are an integral part to the industry's control of quality and compliance, there are still challenges whose solutions have yet to be uncovered. New insights are demanded every day. The Industry Reports are disturbing:

- FDA Warning Letters have increased dramatically in recent years. In fact, the FDA has recorded a record-breaking pace for 483's—**issuing 10,000 citations a year, one every 52 minutes.**[3]
- The number of FDA regulated product recalls has more than doubled over the last five years. **Since 2005, Center for Devices and Radiological Health (CDRH) recalls have accounted for 30% - 40% of all FDA recalls.**[4]
- Poor manufacturing quality is most frequently a result of poorly executed processes. It has been reported that you can essentially **spend $500K a year on compliance or $300M on an FDA consent decree.**[1]
- The GAO has found that approximately **40% of drug shortages resulted from quality concerns** with shortages rising in recent years **while relying on incorrect SOPs.** This is a stark reminder that the FDA's Current Good Manufacturing Practices (cGMPs) only provide minimal standards that manufacturers must meet.[5]
- Increasing numbers of global regulators and regulation complexity, outsourcing, price pressures, and compressed time to market—all can lead to quality and compliance failures. **Two of the Top 10 Pharma deficiencies reported by the FDA were related specifically to ineffective inspection and maintenance procedures.**[3]

The Engelberg Center for Health Care Reform at Brookings reports:
The extent to which standardized quality metrics can meet the FDA's goals depends largely on how these metrics are defined and interpreted. In fact, manufacturing disruptions are most frequently a result of failures in manufacturing quality.

Finding a new way to look at a challenge may be the key to finding an effective way to address it.

Don’t Placate. Innovate.

Quality is much more than vigilance. It is a proactive culture in system building and preparedness that can preempt even the biggest risks. A minimal level of compliance should NOT be the goal. Quality must be managed not only with Attention but also with Intention—not merely measuring failure but possessing a clear vision for improvement.

Proactive collaboration with suppliers can help significantly. Target new improvements. Focus on new ways to uncover and solve continuing issues. The public’s expectations are rising. Yours must as well.

Decisions should be made to target actions that continuously improve processes, reduce waste, increase efficiency, prevent future failure, and enhance knowledge. When taking actions to reverse dangerous trends, a company becomes an anticipating organization rather than a reactive one. Anticipation is power.

Compliance should not be seen as a hurdle. It is an opportunity. Quality should be a source of renewal for the industry—inspiration for improvement. Probe for root causes. Corrective and Preventative Actions (CAPA) should be an integral part of any quality and compliance program. Hesitation to update/improve outdated manufacturing processes, methods or equipment will inevitably lead to monetary damages and patient risk, some catastrophic—as well as serious agency actions.

When a quality or compliance failure occurs, regulators will demand the changes, and the associated time and cost to accomplish these improvements will be much higher.

Too often, failures are attributed to individuals rather than being traced back to process or systems. Problems are not solved by looking for scapegoats. Neither are they solved with a “head in the sand” approach. “If we dig too deeply into quality issues, we may learn something we are better off not knowing.” “If it ain’t broke, don’t fix it.” Change is perceived as unneeded because “as is” is “working.”

Your company’s bottom line is a function of Process and ROI. Lack of investment today will increase the risks of tomorrow.

Five Ways to Overcome the Dangers of Incorrect SOPs

Audit Current Processes to Identify Gaps & Outdated Protocols	Gaps can be found even in the most thought-out procedures. Attention must be given to the steps "in-between." How does each procedure affect other procedures, and other processes? When was the last time a given procedure was updated? Risk Analysis and corrective action also demand Change Control. Even minimal change should be reviewed to ensure there are no gaps in the system that could negatively affect quality and compliance standards.
Understand the Costs and Risks	There are risks that involve costs, but there are other risks as well—to customers and to the business itself. Avoiding shutdowns, and warning letters are just the beginning. Recalls, fines, and extensive costs for corrective measures can ultimately become a far greater expense—not to mention a loss of brand credibility and industry position.
Be Proactive	Improvement comes about first with a recognition that any process can be improved. In fact, it must be improved to keep up with this fast-paced and growing industry. A commitment to change is at the core of what is referred to as a "Culture of Quality."
Invest in Technology and Innovation	There is no substitute for investing in new technology, as it is crucial to improving your systems and products. Using a process or equipment simply because it's been used previously, or because of concerns about the investment requried, is short-sighted and can cost a great deal in the long run. Prioritizing investment in equipment that has not seen technological updates in the longest period of time will help you to rationalize your list of areas to focus on.
Address the SOPs Ripe for Improvement	Sometimes referred to as "low hanging fruit," these are changes in technology, processes, or equipment/replacement parts that can be upgraded for maximum impact with a minimal amount of bureaucracy, time, or investment. These more easily-made improvements can often be executed without concerns surrounding significant Change Control issues. Prioritize opportunities that can be categorized as like-for-like, or that meet functional equivalency requirements. Focusing on these areas will reduce your overall risk and optimize your investments.

References:

1 Expert Briefings, March 2013
2 Blue Mountain Quality Resources, October 2013
3 U.S. Food and Drug Administration (FDA), December 2014
4 FDA Medical Device Enforcement Report, Greenleaf Health LLC, January 2013
5 The Engelberg Center for Health Care Reform at Brookings, May 2014

Acknowledgements:

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See the top areas of focus for improving SOPs.