



RETHINKING THE QUALITY MINDSET/ COMPLIANCE DYNAMIC

By Maxine Fritz

In the health sciences industry, old mindsets can be hard to break.

The perception has long been that quality is born out of compliance. Today's business environment offers another perspective. Over the past 10 years, the industry has dramatically changed due to globalization, increased competition, cost constraints, demands for efficiency, supply chain complexity and processes, and product complexity. Consequently, the industry's approach to quality must adapt as well.

Instead of asking what the minimal requirements are for regulatory compliance, the question should be how to improve quality holistically as an organization. Companies need to think in terms of minimizing inconsistencies early and often throughout the manufacturing and business process. It must take on a quality mindset to compete and prosper.

THE OLD MINDSET: *"Good compliance always translates to good quality."*

Regulations are a good starting point in that they meet minimal requirements. They should not, however, represent a company's mindset in terms of quality. In fact, quality issues—not regulations—account for two-thirds of drug shortages.

The upfront costs of having a quality mindset can seem expensive. Yet in the long term, it is less expensive than having to address a compliance issue. At the low end, a regulatory action can cost a company over \$1 million dollars (or more if products are exported).

For example, let's say a manufacturer can no longer ship products to foreign markets until they are found to be in significant compliance. Conservatively speaking, the compliance process could take 12 months. In addition to

lost revenue, there could be a loss of customers, dropping stock prices, numerous recalls and more. All of this could have been prevented if a quality mindset had been incorporated beforehand throughout the organization.

THE OLD MINDSET: *"We don't have the size or people to support a proper quality system."*

A quality mindset is an approach, not a department. From the executives to the production workers, it is a mentality that should exist and be practiced at every level of an organization. Instead of dwelling on the symptoms of an issue, a quality mindset addresses the source. The goal is to continuously identify and correct the root causes of problems by:

- > Focusing on quality prior to compliance or enforcement
- > Taking measures to reduce human error
- > Investing in aging facilities, utilities and equipment

A company can invest in quality now, which inevitably leads to compliance anyway, or spend millions of dollars trying to correct problems later.

THE OLD MINDSET: *"Process improvements work better in theory."*

This is true IF the effort is not constant. For any leader, flawless execution should always be the objective to sustain a quality mindset. Those who lead need to understand that process improvement systems, like Six Sigma (6σ), are a means rather than an end. By implementing Six Sigma tools and techniques, organizations can expect 3.4 defects or less per million opportunities.



In addition to improving product quality, compliance and the bottom line, Six Sigma management strategies can also help companies focus on the building blocks that make up the quality mindset. These include:

- > Understanding human error
- > Evaluating data integrity problems
- > Optimizing processes
- > Understanding the reasons for poor quality
- > Preparing for inspections
- > Maintaining aging facilities

REPLACE OLD MINDSETS WITH A QUALITY MINDSET

Talk with NSF International. Our health sciences team knows establishing quality mindsets is hard. We also know it is doable. NSF understands the challenges facing the industry because process improvements are at the core of our expertise. We have helped companies of all sizes, from around the world, lay the foundation for creating a quality culture, one building block at a time.

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Maxine Fritz has 25+ years of combined FDA, industry and consulting expertise and is responsible for overseeing the Pharmaceutical practice at NSF Health Sciences, serving in both a technical and management role. Ms. Fritz works with clients in the pharmaceutical, biologics, biotech and medical device industries to develop quality assurance, manufacturing and regulatory strategies for compliance with FDA regulations. She conducts and oversees regulatory gap analyses, assists with the development and implementation of quality systems, and develops and implements corrective action plans to address deficiencies identified by regulatory agencies. Ms. Fritz has successfully managed, resolved and consulted on large complex compliance projects including corporate warning letters, mass seizure, consent decree(s), Application Integrity Policy (AIP) prosecution and import detentions.

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