Life Science Leader
The Industry's Essential Business Source
FEBRUARY 2013
LifeScienceLeader.com

INDUSTRY LEADER

Industry Leader

The Intersection Of Business Decisions With Quality Risks

Effective business strategies accurately weigh opportunity against risk. Life sciences companies, in particular, often overlook a key factor that can easily unbalance the opportunity/risk balance: How will bottom-line business decisions affect product quality?

More than one CEO, confident in the company's compliance policies and practices, has been blindsided by a product recall, safety alert, or curt warning letter from the FDA citing quality failures. A common denominator among these organizations is a narrow focus on compliance rather than a broad emphasis on quality. Compliance and quality are not synonymous, a point vigorously promoted by the FDA in its "Case for Quality" initiative, which calls for companies to adopt a view of compliance as one part of achieving overall quality rather than the ultimate goal. To do that, companies need to recognize the interrelationship of product quality and business decisions — and then take practical steps to address the potential risks created by the intersection of the two.

RISKY BUSINESS

Strategic business decisions — mergers, acquisitions, market expansion, outsourcing, cost-cutting, corporate restructuring — are all developed under the gun of a pitching global economy, regulatory twists and turns, legal and illegal competition, and social upheaval. The opportunity/risk balance is identified and analyzed by teams of experts in a variety of departments/areas. Yet, even though the success of any decision is inescapably tied to the quality of its products, the Quality Department is often missing from this roundtable of experts, called in only after the decision has been made. Tearing down the silo that separates "quality" from "business" is the first clear step in achieving the FDA's goal of a quality-based viewpoint. The second step is factoring the potential that quality impacts into the decision itself.

Product quality can be affected by virtually any business decision, but consider the potential impacts created by just three:

- Mergers and Acquisitions: Investigations of quality-based risks are often guided by past events such as product recalls, warning letters, safety alerts, or patient litigation. Instead of looking backward, quality questions must focus forward. Are there adequate resources committed to integrating the two organizations? Is there adequate manufacturing capacity for new product lines? Will additional production lines introduce potential contamination, climate control, sterility, or handling requirements? Will consolidated supply chains add single-source risks?
- Cost Cutting: Quality issues are attached to virtually all cost-cutting proposals. If one plant is closed, can production be moved to another plant without major structural, environmental, or operational changes to the facility? Will a shift of production require new, potentially unfamiliar suppliers for transportation and warehousing? Will quality be a priority, and will there be adequate resources despite cost-cutting measures?
- Headcount Changes: Major layoffs have been blamed for quality failures, often because of shrinking quality assurance resources and fewer trained employees, but a rapid increase may also signal concern. Whether or not the new employees are adequately trained is the obvious issue, but a rapid increase may also suggest a too-quick expansion of production or products. Is production increasing more rapidly than new employees can be integrated into the system?

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ECONOMICS OF QUALITY

Historically, medical product quality has been assumed if compliance is maintained. Companies can no longer afford that assumption. In its "Understanding Barriers to Medical Device Quality," the FDA pointed out, "The costs of negative quality events have risen due to increasing regulatory, legal, and media attention." Supporting that point, the study provides data that shows an average drop of 16.8% in company share prices due to quality issues. While the FDA report refers specifically to medical devices, the same risks and relative costs could apply across the life sciences industry.

The FDA's "Case for Quality" picks up where "Understanding Barriers" left off. So far, the initiative simply illustrates the FDA's plan to encourage more quality-centered thinking in the life sciences industry. With product recalls and questions of quality rattling patients, prescribers, and payers, the industry has good reason to embrace a strong quality-based perspective toward its operations.