How do enterprising manufacturers stay ahead of the compliance game?

Best practices to turn risk-based product compliance into a proactive process

be enterprising

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Executive summary

For most people, when the subject of regulatory compliance and risk management comes to mind, it usually evokes feelings of fear, uncertainty, and doubt as to how well their organization is prepared for government scrutiny and any number of worst case business scenarios. Questions enter the mind such as: Have we developed the proper procedures that will ensure product compliance? How can we measure and actually know if we are within the regulatory guidelines? Do we know our current compliance related exposure within our industry? Are there new rules in legislation that we should be planning ahead for? Do our systems help or hinder us? These concerns exist in large part due to the fact that there have been so many business cases reported highlighting what can happen if a company has not proactively planned or guarded themselves against the potential pitfalls. Whether it is out-of-conformance operating procedures or non-compliance with new laws, the impact can not only be extremely costly, but can do long-term damage to the reputation and viability of the organization.

These issues can quickly put the executive team on the defensive and relegate the focus of risk management and compliance initiatives to that of simply cost containment and penalty avoidance. While these objectives are important, companies can turn risk management and compliance into a proactive process that assists in building a stronger company image and achieving a competitive advantage in their market. Companies that do the minimum or just appear to be compliant are at far greater risk of customer or regulatory backlash compared to those that are continually striving to improve their compliance. There are numerous examples of companies that are proactive and use financial regulatory mandates to improve processes, not just improve reporting, and have reduced costs and increased their ability to meet future mandates.

Manufacturers should look to move from just being reactive to actively managing and ultimately proactively designing compliance into every initiative. Systems and operating procedures play a critical role in making this transition. For companies with repeatable and auditable systems and processes, they can at least improve their ability to mitigate regulatory incidents. These systems and operating procedures allow a company to quickly identify issues, assess the risk and resolve them. Resolving issues in a sincere manner with a clear plan for resolution will often cause customers and partners to stand by a company in difficult times.

Consider the Tylenol incident in 1982, when seven people in Chicago, Illinois died after ingesting Extra Strength Tylenol capsules that had been laced with potassium cyanide poison. Johnson & Johnson, the parent company of McNeil Consumer Products who produces Tylenol, was already mandated by the U.S. Food and Drug Administration (FDA) to have strict quality procedures and be heavily invested in compliance. Instead, J&J did not let short-term profitability concerns stop them from focusing on the well-being of its customer base. They responded quickly by alerting the media, hospitals, and distributors, and immediately stopped further production, removing over 30 million bottles of the product from store shelves at a cost of over $100 million US. Although the incident took a huge toll on their short-term profitability and market share, they were able to save what was considered to be their most profitable product and brand. With a reputation in quality already in place and an ability to quickly take action and put customer well being ahead of financial gain, J&J quickly regained their consumer confidence. Today, Tylenol remains a leading pain reliever brand.

In 2007, several large scale recalls of products sourced with a lowest total cost mandate show the limitations of not addressing compliance. For a few cents of projected savings, companies have seen their product brands, their image and their financial stability crushed.

The Tylenol incident and the numerous 2007 consumer recalls are good examples of how compliance and risk management goes well beyond the internal operation, and spans the entire supply chain. A comprehensive strategy should include three primary dimensions: An Internal Dimension, including those variables you can control; An External Dimension, including factors outside your control; and a Customer Dimension, including supply chain factors outside your control but that you can influence.

While it is common for companies to launch compliance and risk management initiatives focused on defensively reacting to external pressures, it is critical to involve and consider all constituents in your strategy. Equally important is recognizing that compliance and risk management is not a project, but rather a process that must be monitored and adjusted on an on-going basis.

The compliance mandate

Over the past few decades, the pace of introducing new government regulations and compliance guidelines has accelerated significantly, and is not expected to slow down anytime soon. Partially as a result of consumer demand for economic, environment and social responsibility, shifting of the burden of safety to manufacturers from governments many new laws are helping to fuel tighter restrictions on manufacturers. These new restrictions and laws have increased costs and have mandated changes at all levels of the organization. This has required re-tooling at the plant floor level, re-evaluating materials and suppliers, re-examining of how products are introduced and marketed, and driving many new administrative procedures. As a result, companies are responding in a variety of ways to these events, and often times in an ad hoc, reactionary manner. The proliferation of compliance and risk management concerns calls for companies to take a fresh look at all aspects of the issue. One way to view the matter is to build a strategy that encompasses three primary influences.

1. **An Internal Dimension** that includes all of the supply chain facets under your control, such as:

- Product ideas, designs and lifecycle management processes
- Selection of the raw materials and ingredients as well as the suppliers you choose
- Quality Assurance and testing standards
- Operating procedures and business processes
- Compliance strategy and enforcement
- Investment in production, distribution and transportation capacity
- The core values established for the organization which help to guide decisions and dictate how the company is perceived in the market

2. **An External Dimension**, which includes those facets out of your control, such as:

- New government regulations and restrictions
- Trading partner mandates such as reductions in consumer packaging, product labeling and delivery requirements
- New technology introductions such as RFID or E-pedigree, as well as electronic distribution of product updates
- Macro economic factors, foreign tariffs and global political issues
- Weather conditions that can interrupt production or delivery and can influence supply channels and change demand requirements instantly

With new laws like REACH or as companies look to increase the use of strategic partnerships from product design to production and distribution, strategic partner compliance will be as critical as internal compliance.

3. **A Customer Dimension**, which, although is outside your direct control, can be influenced based on how well your company builds relationships with your customers and establishes customer centric values and business ethics. The customer dimension considers:

- The active participation and involvement of the customer in product design and development
- Jointly managing the supply and demand factors

With many customer or retailers mandating improved sustainability or "green" products, companies that are proactively designing in compliance will have a competitive advantage and will minimize their compliance exposure.

Your business processes should encompass all three dimensions, internal, external and customer, in order to sustain compliance and risk management. Taking a proactive stance of these factors can create good will with customers and market influencers, providing a reserve of support in the event of an unexpected compliance issue or product recall. Companies that take this approach, and actively institute socially responsible policies and conduct themselves in a forward thinking manner can not only stay ahead of the compliance game but also can win new business.

Consider companies such as Dell computer that includes "no postage required" return envelopes with new printer cartridges, so that the used cartridges can be easily returned for recycling at no added cost to the customer. In other cases, many manufacturers are using recycled packaging materials or locally produced ingredients, or insuring that products are not produced by offshore contract manufacturers considered to be low-wage sweat shops or those that employ children. While some of these policies are driven by the rising costs of raw materials, the rising cost of energy, the expense of waste disposal, and changes in taxation laws, many companies are beginning to see the benefits of conducting a "Green" business from a customer acquisition and retention point of view. Not only does this approach provide a strong foundation of positive public relations and improved customer loyalty, but it also positions the company as one that is already in compliance when new rules are introduced. This can be used as a significant competitive advantage, and should be integrated with sales and marketing efforts. Being green and being profitable are not mutually exclusive goals.

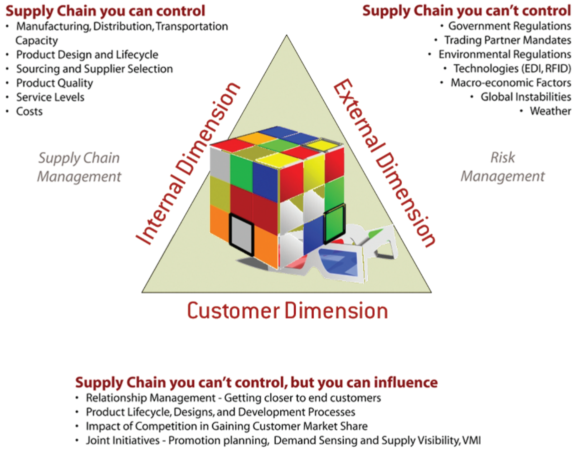

Figure 1. A multi-dimensional approach to compliance and risk management

Managing compliance and risk

In the past, compliance and risk issues have seemingly gone in cycles, with financial compliance and corporate ethics receiving greater attention in recent years with many companies engaging in accounting fraud and misuse of company funds. Regardless of media attention, the three dimensions of compliance and risk are always active and need to be monitored and managed. Companies typically fall into one of several categorical approaches to managing compliance. Unfortunately, too many find themselves with inadequate systems and fall into the reactive mode of compliance where they are firefighting. Reactive compliance is dictated by responding to issues as they arise, and focusing on keeping costs and resources thin in order to realize short-term gains. With the appropriate operational systems, organizations can start to adopt an active mode of compliance and build processes and procedures to manage the issues and associated transactions more efficiently. As an example, integrated validation and workflows allow companies to stop shipments to company locations based on "regulatory lock out" rules or stop procurement of a material to a plant without adequate regulatory handing capabilities. However, in order to turn compliance and risk management into a competitive advantage and begin to strengthen the company brand, companies need to adopt a proactive mode of compliance.

The proactive mode ensures that compliance and risk management factors are built into the design of products, the business processes, and each department's business plan. From product lifecycle management to sourcing and supply chain planning, Enterprise Resource Planning (ERP) and Enterprise Asset Management (EAM) provide continual feedback and integrated compliance processes to ensure that you do it right the first time and every time. In order to achieve a proactive stance on the issue, it is important to establish a senior level position, reporting to the President, which can develop and maintain a company-wide strategy as well as sustain the effort and stay ahead of potential new requirements. Whether it is an Executive Vice President of Compliance and Risk, or a Chief Compliance Officer, manufacturers must make someone accountable for driving and guiding the effort.

In developing a strategic plan as the Chief Compliance Officer (CCO), there are a number of key elements that need to be considered, including: industry specific mandates; country and region specific regulations; distribution and trading partner guidelines; internal product development procedures and practices; and many customer influences.

As a process, identifying the external influences as the first step may help to guide many of the internal processes and ensure the base level requirements are being met. Industries such as Electronics, Food & Beverage, Pharmaceutical, Chemical, and Automotive in particular have many externally imposed government regulations that need to be addressed. In the electronics industry, there are several standards, specific to the European Community that affects any manufacturer shipping products to EU countries. U.S. companies that proactively work to address these EU standards, even though they may not be distributing products outside of North America today, can not only get a jump on the competition but can be perceived to be "Greener" than their competitors in their local market if they address these requirements. The CCO should be keeping a close eye on these types of initiatives, not only because they may apply to their market in the future, but also may build a stronger company image based on best global market practices.

Examples include the Waste Electronics Equipment Directive (WEEE), which is a directive set by the European community, Korea, Canada, and California several years ago to regulate the collection, recycling and recovery of potentially harmful electronics materials. Similarly, RoHS, the directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, was established in the EU, China, and Korea, to restrict the amount of mercury, lead, and cadmium used in products. Other initiatives in the chemical industry include GHS (Global Harmonization System of Chemical Classification and Labeling), and REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) for safer handling of chemical substances from one party to another.

When working on the internal dimension of risk management, it is important to establish a founding set of business ethics and values that every employee can work from. For companies that are lagging in compliance or best in class companies, risk based compliance allows companies to focus on their greatest areas of exposure and continually improve. Balancing risks with potential costs or business improvements can provide clear project justification and ROI. Setting tangible goals and performance measures that are clearly communicated and reviewed with staff on a regular basis will ensure that the goals are reinforced within every aspect of the business. Often overlooked, the internal plan should set a standard for how employees are treated and valued, including how they are trained, measured and rewarded for meeting their goals. An employee, who is shown a good example of how they are treated by their own company, will establish a solid foundation for carrying that posture and value system forward to the customer and supplier base.

There are several regulations that are designed to help protect the employee, such as Material Safety Data Sheets (MSDS) and the OSHA Employee-Right-To-Know (ERTK) Act which requires employers to identify, document, and publish any hazardous substances, harmful physical agents and infectious agents present in the workplace as well as provide information and training to employees who are "routinely exposed" to those substances or agents. However, employers should look beyond merely complying and seek ways to eliminate any potential employee, environment, and customer hazards.

Working with a motivated staff that is valued by their employer will become a tremendous asset as the company looks to design and build new products. Designers will likely have a greater sense of responsibility for finding ways to balance marketability with sensitivity to potential hazards. More than ever, both the government and consumer constituency have a heightened sense of awareness for potential hazards and are much less tolerant of safety problems. By having the CCO as a member of the team at the outset of the product design process, time can be saved down stream in the testing and approval process. As most manufacturers have learned, having quality assurance and field service staff involved in the design phase can prevent costly redesign and reworking of specifications. Likewise, by involving the compliance and risk management staff, many safety and potentially out-of-compliance issues can be addressed early and save valuable time, money, and possibly the company's reputation if the issues are not discovered early enough. With the clear executive mandate, compliance aware systems and processes, and trained personnel; compliance can be transformed from a department to an "Army of Chief Compliance Officers" and overwhelm the competition.

To fully exploit your emerging compliance capabilities into sustainable competitive advantage, manufacturers need to leverage the customer dimension. Customers are stronger allies and advocates than most manufacturers give them credit for. With so many more choices in products than ever before, customers are more selective, but they have also developed an insatiable appetite for new and improved products. By working closely with customers, manufacturers have the opportunity to share their value system and learn more intimately what the customer is looking for, whether it concerns pricing, product capabilities, services and after-market options, or distribution vehicles. Over the past several decades the average consumer has seen dramatic changes in regulations designed to protect them. They have also been afforded greater access to information, alerting them to potentially dangerous materials and substances. Therefore, there has been increased pressure from consumers and customers for even tighter controls.

The bar continues to be set higher and higher for manufacturers to not only comply with government mandates but to also address possible future mandates that are in the media spotlight. Manufacturers that can be a leader their market in responding to these customer or consumer-driven initiatives will likely gain a competitive advantage. Consider auto manufacturer Volvo, who was first to introduce three-point seat belts as a standard feature in 1959 and the first rear-facing child seat in 1967, among many other safety innovations. These are innovations that significantly preceded government mandated requirements and established the Volvo brand as a safety leader. Their continued focus on safety, and a core value system that places a priority on the well being of their customers, sets them apart from their competitors.

Taking a balanced approach

The compliance and risk management effort for any company, whether it is making electrical components, packaging food, or processing raw materials, has become increasingly complex. How can a company balance the increasing risks and cost of compliance with the escalating expectation of quality and safety from government and consumer constituents, and at the same time grow a profitable business? In addition to instituting forward thinking core company values and best practices, companies must also implement systems to improve their efficiency and reduce the cost of compliance and risk management. Implementing a risk based compliance strategy allows companies to focus on the areas of greatest exposure and potentially the biggest area of competitive advantage. Implementing business systems will not only accelerate the capture of transactions and save time, but they can also be used to keep the workforce on track with the business planning and execution activities that are designed to maintain compliance. In more and more environments, it is becoming a mandatory requirement to keep better records, and as a result, organizations are turning to business system vendors to apply new technologies that help maintain compliance.

Some organizations, particularly publicly traded firms, have turned to improved control systems out of necessity. As an example, the Sarbanes Oxley Act of 2002 (SOA) also commonly referred to as SOX Compliance, requires public companies to maintain more comprehensive financial records, respond to shortened filing deadlines and disclose greater financial details in order to provide a more complete picture of financial health and status. Although targeted at publicly traded companies, this law sets a new standard for all companies large and small. Even privately held companies can benefit from adopting practices that promote the detailed documentation of their finances and business processes, particularly for those who may seek to be acquired or "go public" in the future.

New business systems are also being driven by production level standards such as the Toxic Substance Control Act (TSCA, TOSCA) which provides the Environmental Protection Agency (EPA) the authority to regulate the manufacture, distribution, and use of chemical substances. TSCA requires any person who manufacturers, processes, or distributes in commerce any chemical substance or mixture to keep records of significant reactions to health or the environment that allegedly were caused by the chemical. Records concerning health effects on employees must be kept for thirty (30) years and other records must be retained for five (5) years. Similarly, medical device manufacturers, biotech companies, and many other FDA-regulated industries must implement, stricter controls as defined by the FDA 21 CFR part 11 regulation. Often times, the mandated requirements are largely common sense practices which will help your company better itself as it moves toward a quality approach using continuous improvement. And in the case of FDA regulations such as the Good Manufacturing Practice (GMP, cGMP) under the Federal Food, Drug, and Cosmetic Act, requirements are general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides flexibility, but also requires that the manufacturer interpret the requirements in a manner that makes sense for each individual business environment. Being proactive in internalizing new regulations and making product development decisions based on new research can help to build a stronger brand and win new customers. For food manufacturers, this can mean moving beyond simply updating their labeling to identify Trans-fats and Allergens, but to work towards removing them from their products whenever possible.

Summary

Today, companies can benefit from taking a fresh approach to compliance and risk management that goes beyond cost containment and lawsuit prevention, and turn it into a competitive advantage. Consumers, trading partners, and employees hunger to work with, and buy products from, companies that value long term, trusted relationships above short-term profits. By focusing on product designs, materials, and quality and safety capabilities that exceed expectations, manufacturers quickly set themselves apart from their competitors. However, achieving these goals requires commitment from the top of the company, and must be promulgated throughout the organization. A good first step is to demonstrate a commitment to proactively addressing the issue by appointing a Chief Compliance Officer. Setting the tone, by establishing core values that serve to protect and enrich employees and customers, will promote employee buy-in and build customer loyalty. You can move from a reactive compliance team to a proactive army of chief compliance officers and turn compliance into a competitive weapon. This will help to also sustain the effort, since compliance and risk management is an on-going process and will take time to realize the anticipated benefits.

Recognizing where your organization is in its evolution in becoming a world-class manufacturer, whether that is as a reactive, active, or proactive company, can help you to identify areas of improvement. As progress is made towards moving up the scale, communicating that progress will help keep employees motivated and customers on your side. Many customers want to know that there is sincere interest by producers in reaching new heights of quality and safety, and will forgive those organizations striving for excellence more readily in the event of a misstep. Countries such as the United Kingdom have launched government programs such as the Sustainable Development Strategy in light of growing concerns surrounding the negative effect that the world's consumption patterns are having on the environment and the climate, such as global warming. The goal is to direct industry constituents such as manufacturers to reduce greenhouse gas emissions, and increase their use of electricity produced from renewable energy sources. EU REACH laws are shifting the burden of safety on to manufacturers, while providing a better quality of life for everyone, both in the developed and the developing world. Sustainable Development serves to integrate economic development, environmental protection and social responsibility. As a result, sustainability can provide companies with a holistic approach to address the moral and ethical values of our consumers and other key stakeholders, along with their simultaneous desire for a higher and more rewarding quality of life. These measures are not only noble, but will assist in building long term customer loyalty and develop more highly motivated employees. Your re-energized staff will help to fuel higher levels of product quality, innovation, and secure long term company profitability and viability. By integrating the three dimensions of external, internal and customer driven influences, your compliance and risk management efforts will put your organization at the forefront of your market and set you apart from your competitors.

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