Tech-Clarity

making the value of technology clear

Regulatory Compliance Across The Product Lifecycle

Reduced Risk and Lowered Costs Through Proactive EH&S

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Executive Overview

The value that Product Lifecycle Management (PLM) initiatives provide to manufacturers comes in many forms, including: faster introduction of products, reduced product cost, increased product sales, higher product quality, reduced waste and more valuable product portfolios. These are some of the more positive aspects of PLM that people like to talk about. One area that doesn't get as much attention is compliance. Regulatory compliance, while nobody would dispute the critical need for it, is not as exciting or enjoyable to discuss. The problem with leaving compliance unspoken is that a significant amount of the value associated with Product Lifecycle Management is dependant on addressing compliance in a cost-effective manner. In fact, all of the benefits of PLM could be quickly erased by significant non-compliance events that impact the company through fines, penalties, negative publicity or prohibition to sell a new product in key markets. Compliance risk may not be a glamorous topic, but it is critical to the development and sale of profitable products and responsible, sustainable corporate profitability.

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Few would disagree with placing compliance to regulations as a goal for a PLM initiative, but at what level of priority? At what cost? For which jurisdictions? Without proactive management, regulatory problems are often found at the most inopportune times. This paper will review real examples of "moments of regulatory crisis", their impact on the business, and the value that focusing on compliance throughout the life of the product can provide. Design for compliance and proactive monitoring can help companies navigate the myriad of regulatory requirements required for profitable business.

Compliance Is Critical to Sustained Product Value

Throughout the product lifecycle companies must ensure that they remain in compliance with governmental regulations and internal corporate guidelines. Without a compliance strategy, the PLM value proposition is at risk. For example, companies have recognized the strategic value that getting products to market faster can offer. Accelerated time to market is a frequent goal that companies look for from better management of products, and companies have invested in compressing product development cycle times, supply chain efficiencies, more effective product commercialization and other methods to make their products available before their competition can react. Compliance is critical to time to market. If compliance is not designed into the product from the very beginning, costly time can be consumed redesigning or reformulating the product to address compliance. A common scenario for redesign occurs when expanding a product to a new market. Regulations can vary significantly based on where the product is being sold, based on different regulatory bodies and jurisdictions. If a designer develops a product without visibility to its eventual markets, restricted materials may be included in the product and force significant design rework. These design flaws, if they are not caught early in the process, can cost companies significantly in time to market.

Without a compliance strategy, the PLM value proposition is at risk

Minimizing the cost of a formulation or design is another key benefit sought from PLM initiatives. By actively managing both internal and supply chain costs in the product design phase, companies have been able to significantly reduce the cost of their products. This reduced cost provides benefits in increased margins or increased competitive pricing if the savings are passed along to the customers. Again, compliance is critical to achieving the benefits. If product designs are developed that violate regulatory rules, the product may have to be modified to comply after it has been released to the market. Alternatively, the design may result in significant additional cost to ensure compliance in the form of additional pollution control equipment during manufacturing, protective packaging, rigid storage requirements, and specialized waste disposal. Once a product is released and in use by customers, the degree of flexibility that the designer has to make changes is drastically reduced. The sooner that compliance issues are addressed, the more options the designer can tap to keep product costs optimal. As time runs out, so do options, and the cost goes up. These costs are not limited to ingredient or component costs. Increased handling, transportation, manufacturing and regulatory fines are other areas of cost that can quickly erase the value that least cost designs can provide.

A final example of additional value of is improved value of product portfolios. By increasing the level of innovation within a company, and bringing more differentiated products to market, companies can increase their value through improved products on the market. Improved products increase sales and should lead to increased company valuations. But what value does a reputation for leading and innovative products stand against an environmental or regulatory public relations crisis? In the same way that the net present value of a new product idea is discounted by risk factors, perhaps company valuations should be discounted based on regulatory risk.

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For most of the proven value that can be generated by an effective PLM program, there is risk from non-compliance that can negate the benefits of PLM. While the benefit and the potential risks are not always clearly related, the comparison of value to potential downfall serves the purpose of highlighting the need for regulatory compliance within a PLM strategy. Companies that invest in PLM and ignore compliance issues may be getting their product development house in order, but it may turn out to be a house of cards if there is not a solid foundation that minimizes the risk of non-compliance.

PLM Benefit	Consequence of Noncompliance
Improve Time to Market	Product Introduction Delays Design Rework for Compliance Delayed Rollout to Geographies
Reduce Product Cost	Last Minute Design Changes Need to De-Optimize Designs Fines and Penalties Unforeseen Supply Chain Costs Manufacturing Process Changes Unidentified Pollution and Exposure Control
Reduce Development Cost	Design Rework Manual Creation of Documentation Manual Effort to Catch Flaws
Increase Value of Product Portfolio	Limited Markets for Products Product Value Discounted for Risk Company Value Discounted for Risk Negative Public Perception Criminal Prosecution Company Not Seen as a "Green" Company
Improved Innovation	Last Minute Design Constraints Product Delays or Cancellations
Increases Success Rate of New Product Development Projects	Missed Window of Opportunity Products Not Valid for Geographies Product Registration and Limitation Unforeseen Pollution Control Issues
Improve Handoff From R&D to Manufacturing / Outsourced Production	Last Minute Labeling Problems Last Minutes Repacking Problems Unidentified Health Risks Unidentified Safety Risks Delays for Regulatory Documentation Delays and Extra Costs for Transportation Right to Know Requirements not Met General Compliance Documentation issues
Increase Product Quality	Product Performance Reduction from Changes

Table 1: Consequence of Noncompliance on PLM Value
Source: Tech-Clarity

Non-Compliance Surfaces at Inopportune Times

Compliance is not coincidental. It requires knowledge of the applicable rules and regulations and adherence to those constraints throughout the design and production of the product. Compliance starts with a core of knowledge, and stretches throughout the lifecycle of the product. Failure to focus on addressing regulatory requirements can lead to regulatory design flaws. Regulatory design flaws, when discovered in the design phase of a product, are typically easy to correct. The later a problem is found, however, the more costly it will be to address. When design flaws surface at inopportune times, particularly when the product has been sold and delivered, the flaws can escalate into "Moments of Regulatory Crisis". Moments of Regulatory Crisis are points in time where past inattention to compliance issues become critical, and sometimes public, problems. The following examples highlight the impact of non-compliance, how easy the flaws are to create, and how they can be avoided.

Moments of Regulatory Crisis are points in time where past inattention to compliance issues become critical, and sometimes public, problems

Moment of Regulatory Crisis– Found in Design

We'll start with a positive example. This moment of regulatory crisis is, in fact, not a crisis but a nuisance. Before a product has been released to manufacturing and delivered to a customer, the R&D team has more flexibility to make changes.

During the design phase it becomes clear that a new product, perhaps a reagent for medical diagnostic equipment, is not only an excellent product for the US market but also for the European market. The marketing managers state that this product will have a high sales potential in Europe. The problem, however, is that one of the components in the formula is not listed on the European Inventory of Existing and New Chemical Substances (EINECS/ELINCS). There are several approaches to overcome this:

- Notification of the chemical in Europe. This requires extra testing and notification, which may take more than half a year
- Substitute another chemical with similar properties, and try to correct for any resulting change in performance of the product
- Make two similar products, one for the US and one for Europe

If this type of problem is found during the design phase, as in this example, the potential resolutions can be reviewed and selected proactively before the product is released to the US market. If the product had been released without the component being flagged, or if the potential for the product to be sold in Europe is not identified in advance, the options for resolving the problem would have been more limited.

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Moment of Regulatory Crisis– Found in Production

The next regulatory crisis is an internal issue, one that causes internal delays, disruption and expense. A new product was scheduled for production that had been successfully piloted and run in R&D but was not yet in full production at the plant. During the production planning process, a routine check discovered that this product with high expectations for the Italian market contained a new solvent, gamma-butyrolactone (GLB). GLB is on the Italian List of Substances considered as "Drugs". Due to this decision, the use of GLB has to be authorized for this product. This means an uncertainty (will the authorization be given?) and at least a delay of several months before the product can be put into production.

If this type of problem is found in production, the options for recovery are more limited and the potential impact of the problem is greater

If this type of problem is found in production, the options for recovery are more limited and the potential impact of the problem is greater. The resulting change in the production schedule will likely add unnecessary cost, and the product that is not produced was likely destined for delivery to a customer that now must be disappointed. Had this problem been discovered in the design phase, the impact would have been much lower.

Moment of Regulatory Crisis– Found in Logistics

Another area where surprises can occur is in logistics and transportation. Hazardous materials require documentation, placarding and labeling specific to not only the product but also to the transportation mode. This example identifies the challenges that can occur after the product is in production, challenges that can substantially increase costs or decrease product reach. A company was changing shipping modes for a product when they discovered that the product was prohibitively expensive to ship in the preferred way because of its physical properties.

The recently adopted Amendment 31-02 of the International Maritime Dangerous Goods Code (IMDG) has put more severe rules on the segregation of alkalis and acids. Based on the IMDG, a product that contains both a bottle with an alkali and a bottle with an acid in the same box are no longer allowed to be shipped by sea. The product, perhaps a test kit, must be redesigned to ship in separate boxes of the alkali and the acid, to be shipped on separate pallets.

If manual processes are required to review every potential impact of a regulatory change, it is likely that some problem will be overlooked and the disruption will impact the customer as well

This example, which occurred after the product was released, caused a lot of disruption for the manufacturer and for their customers. If the problem was caught earlier, the product might have been able to be redesigned before the new regulation went into effect. If manual processes are required to review every potential impact of a regulatory change, it is likely that some problem will be overlooked and the disruption will impact the customer as well.

Moment of Regulatory Crisis– Found at Customer

According to California Proposition 65 even traces of Dioxane contained in a printing ink (as an impurity in one of the raw materials) make it necessary to put the name of this chemical on the label when sold in California. This printing ink is sold world-wide with only one label which discloses the traces of Dioxane. A customer in Australia discovers that the printing ink contains Dioxane and thinks his health is in danger because of the use of this ink. He sends letters to the trade magazines of his “discovery”, resulting in a damage of the good name of the company. As for almost the rest of the world there are no legal obligations to put the name Dioxane on the label or even disclose it in a Safety Data Sheet, the company could have mentioned this name only on products sold in the State of California.

This example highlights the fact that manufacturers must manage regulatory and compliance requirements across geographies and jurisdictions. By designing the labeling for the most restrictive jurisdiction, the company simplified the management of their labeling, but created a potential problem. The alternative, which requires a greater level of coordination and control, is to develop alternative labeling or recipes to meet different regulatory goals. With accurate, detailed information of requirements by geography the company can better analyze the available options and then implement them effectively.

Manufacturers must manage regulatory and compliance requirements across geographies and jurisdictions

Implementing Design for Compliance

Experience shows us that driving flaws out of processes drives greater quality. This concept is the foundation for many quality programs including Total Quality Management (TQM), Six Sigma and others. In the same way, the process of product design can be improved to prevent moments of regulatory crisis. A moment of regulatory crisis should be considered a flaw in the design process, whether the problem occurs in the physical or commercial aspects of the design. Compliance must be considered a critical outcome of the design process. In order to achieve this, regulatory requirements must be identified and addressed early in the process. For companies that have adopted a gated product development process, compliance should be included in all stages. This includes the very beginning stages of design, before any resources from R&D may be involved. A thorough review of the markets for the product should identify the intended use of the product as well as the geographies in which it will be sold. These are critical design constraints for the designers.

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When designers have all of the appropriate constraints in hand, the next challenge is to ensure that they have the tools available to identify violations to these constraints. The tangle of requirements is far too complex and changes too rapidly for any person to hope to address without automation. Designers should have access to tools that can automatically interrogate their designs and flag potential regulatory issues early in the design process. The ideal scenario would include the ability to instantly view the results that the design would have on product labeling, transportation and compliance issues.

To effectively and efficiently manage regulatory and compliance issues requires a tool that can manage the complexity for the designer, but also a trusted source of updated regulatory information that is integrated into the tool in the form of rules. Although some companies attempt to develop these systems on their own, packaged solutions and services are available. "*Creating a Material Compliance System from the ground up can be a labor intensive and time consuming endeavor that typically yields a solution that does not address global legislation and is expensive to maintain*" says John Phyper, coauthor of Global Materials Compliance Handbook (Phyper, Ducas, Baish – Wiley 2003) and COO at material compliance software provider Atrion International, "*and if not designed and implemented properly, the system may lack key integration points to other major systems within the organization, only address a small portion of relevant legislation, and become outdated within a relatively short period of time*." Based on this level of complexity and the dynamic nature of regulations, the regulatory information and tool are both good candidates to be outsourced to take advantage of industry-level economies of scale. In this way, individual companies don't have to proactively monitor for new and changing regulations.

"Creating a Material Compliance System from the ground up can be a labor intensive and time consuming endeavor that typically yields a solution that does not address global legislation and is expensive to maintain" says John Phyper, coauthor of Global Materials Compliance Handbook and COO at material compliance software provider Atrion International

Implementing Proactive Compliance Monitoring

The compliance checks in the design phase are critical to developing designs that meet current regulatory demands. Unfortunately, the regulatory environment is a moving target. Rules and regulations are in a constant state of flux and revision, and can impact a product anywhere along its lifecycle. Recent regulations, in fact, have begun to place even higher emphasis on the environmental impact of the product upon disposal or recycling. Changing regulations, including trade regulations, must be proactively identified and compared to existing (and sometimes previous) product designs in order to trap potential compliance events. Diagram 1 below, reprinted with permission from Atrion International, provides an excellent overview of the areas that require attention from Proactive Compliance Monitoring:

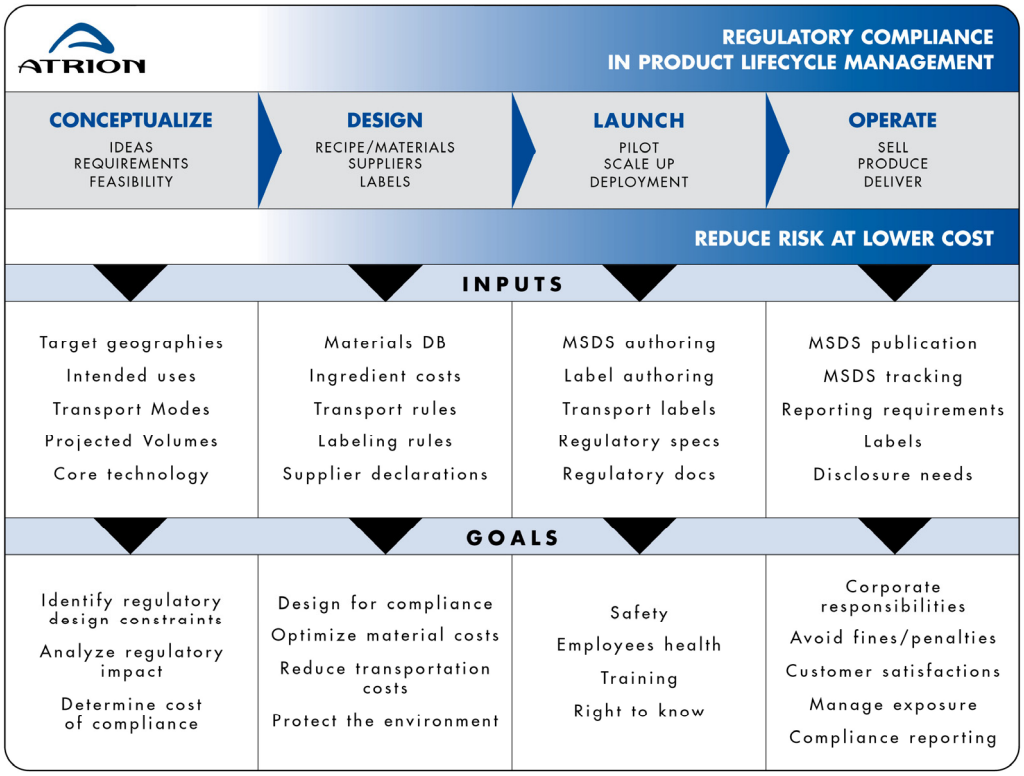

Diagram 1: Managing Compliance in the Product Lifecycle
Source: Atrion International (www.atrionintl.com)

Documenting Compliance

Compliance must not only be implemented across the product lifecycle, it often must be proven. Documentation of compliance is an important aspect of compliance itself. The company should have access to all regulatory rules as well as the proof that they are being adhered to. This reporting must be based on a solid foundation of product knowledge that identifies the specifications and composition of the compliant materials. Standard regulatory reports, as well as ad-hoc analysis required to identify potential future problems, should be readily available. As regulations change, reports should be prepared that display all raw materials and all products that would not be in compliance. Because most regulations have a timeframe identified for compliance, the report can be generated to allow the maximum possible lead-time to address the issues so that optimal design choices can be made instead of last minute temporary fixes with negative consequences like increased product cost. Whether standard or ad-hoc, documentation of compliance shows that the process is in control, and can be as important in many cases as compliance itself.

In many cases, the documentation is the source of compliance. Hazardous and other regulated materials require an increasing amount of information to allow informed decisions for people who are routinely exposed to the substance or for those that may come into contact during transportation or that must respond to spills or other potentially hazardous situations. With increased demand for public safety and public awareness of potential exposure and consequences, product documentation has become increasingly complete. This completeness has place an increased demand on manufacturers to provide accurate, detailed information about their products and the potential consequences of their products. This documentation, which includes identification of raw materials, product registration forms, labels for the product, placards for transporting the product, driver instruction cards (Tremcards) and detailed material safety data sheets (MSDS) or Workplace Safety Cards (WSC) can be a cumbersome manual effort if it does not rely on approved, repeatable and automated processes. For companies that ship products to multiple geographies, the complexity of multiple regulatory requirements in combination with multiple languages can be staggering without technology to assist in the development of the documents. Companies should look for the ability to automate the creation, publication and dissemination of this compliance documentation in order to provide and prove operational compliance with regulatory needs.

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Recommendations

- Include regulatory requirements very early in the product design process to identify design constraints
- Monitor ongoing regulatory changes for existing products in a proactive manner
- Look to outsource the maintenance of regulatory compliance requirements in order to leverage industry level economies of scale
- Embed regulatory compliance into product lifecycle processes and enabling technology to eliminate the variability of how and when compliance is addressed
- Recognize compliance as a corporate responsibility as well as a solid business investment, not as a "necessary evil" but as "competitive advantage"
- To reduce complexity, consider a technology partner that can enable the process with a tool that is pre-integrated with a compliance database
- Acknowledge compliance as a global issue and proactively manage compliance for multiple jurisdictions and multiple languages
- Ensure that all elements needed for the product design are well documented with all relevant regulatory data
- Capture, store and communicate data on national inventory lists, occupational exposure limits values, and occurrence on lists of chemicals that are banned, restricted in use, separately regulated in poison acts, seen as drugs or parts of chemical weapons

About the Author

Jim Brown has over 15 years of experience in management consulting and application software focused on the manufacturing industries. Jim is a recognized expert in software solutions for manufacturing and has broad experience in applying enterprise applications such as Product Lifecycle Management, Supply Chain Management, ERP and CRM to improve business performance. Jim is a frequent author and speaker on applying software technology to achieve tangible business benefits. Jim can be reached at jim.brown@tech-clarity.com.