Tech-Clarity

making the value of technology clear

Issue in Focus: Product Compliance – The Hidden Tax on Innovation

Enhancing Innovation in Formula-Based Companies through Real-time, Automated Compliance Monitoring

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Introducing the Issue

Companies need to develop innovative products – the products that consumers "have to have" – and bring them to market quickly. This is the key to profitability in today's challenging, global consumer markets. Those in highly-regulated industries not only have to innovate rapidly, but do so despite complex product compliance demands from around the world. Companies developing personal care, cosmetic, pharmaceutical, and food products must meet challenging demands from global regulatory bodies concerned only with regulatory compliance – with no thought on how the new regulations will impact product performance, customer appeal or time to market. The implications of noncompliance can be severe – ranging from being blocked from releasing a product in a country or region, to products being pulled from shelves, fines, and significant damage to the brand. In this environment, the successful innovator has to design for both the consumer and to satisfy the various regulatory bodies. World-class product development companies begin to address compliance "day one" of the product development cycle by defining requirements based on global distribution plans. Companies have found that the further into the new product development (NPD) cycle they wait to check compliance, the greater the negative impact that identified issues have on time to market, product performance, cost, internal efficiency, and their ability to roll the product out in multiple markets globally (Figure 1).

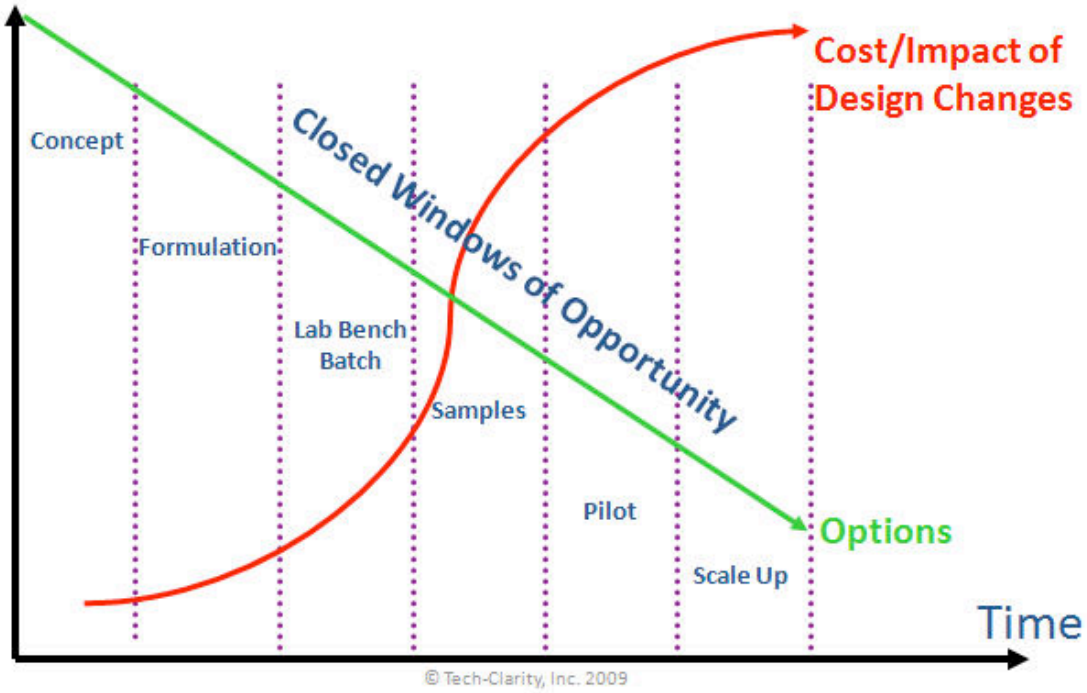

Figure 1: Cost / Impact of Formulation Changes over Time

Leading companies are combating this by opting to "design compliance in" to get the product "right the first time." Without checking compliance early in the lifecycle, products can get through stability and clinical testing before someone discovers they aren't compliant, and designers have to go back to the beginning of the process, losing time and wasting money on testing that must be repeated once the formula is brought into compliance. Even more costly to the business, late compliance issues can put the product launch date in jeopardy.

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Early compliance checking helps identify compliance problems earlier, preventing late changes due to undiscovered compliance problems. Unfortunately, the critical resources that are the source of innovation – chemists, formulators, flavorists, food scientists, process engineers, etc. – are the same people being asked to "design for compliance." By shifting these resources to ensure compliance through brute force, many companies have simply diverted critical resources away from product innovation by placing inefficient and time-consuming compliance demands on their key product innovators. This solves one problem (early compliance), but replaces it with another problem (inability for designers to focus on innovation). In essence, this serves as a "hidden tax" on their innovation resources. Instead of improving product development performance, a poorly implemented, manual compliance strategy reduces development efficiency and innovation capacity – and often results in the development of uninspiring, "me too" products.

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Real-Time Compliance Monitoring

It is not a realistic option to ignore the compliance requirements, nor is it an appealing concept to pull even more time away from product innovation. But few companies recognize the tradeoffs they are making between innovation and compliance because they don't have visibility into the time they are spending continuously making manual checks on product compliance. Because it is typically not well measured, it becomes a hidden resource drain or "innovation tax" on the R&D organization. World class companies are choosing to design compliance into products while relieving the innovator from their

manual compliance burden with a framework of intelligent software-based automation coupled with compliance knowledge that:

- Provides knowledge of global compliance requirements
- Recognizes the full composition of their raw materials, including contaminants (such as naturally occurring trace levels of lead in a pigment)
- Understands the product formula as it is being designed, including the underlying chemistry and the intended product usage (such as product type, FDA category, leave on versus rinse off)
- Checks compliance real-time as the developer innovates, warning the formulator or chemist of potential negative downstream impacts of their choices
- Provides full, electronic documentation of compliance for product registration and audit support

An alternative approach is to design compliance into products while relieving the innovator from their compliance burden with a framework of intelligent software-based automation coupled with compliance knowledge.

This "Issue in Focus" will examine each of these five elements in more detail, and provide a roadmap for companies to streamline product compliance on a global scale through automation. By using the right processes and tools to design for compliance and simultaneously generate compliance documentation, companies can achieve product compliance and meet demands for more rapid product innovation. Even more, they can offload manual compliance checking to the system, thus empowering their key innovators to focus on delivering high performance products to global markets hungry for breakthrough products. Companies that combine early compliance checking with real-time automation are empowered to try more creative designs and explore more new product forms and new technologies, while remaining confident that their compliance infrastructure will keep them out of trouble from downstream compliance issues (Figure 2).

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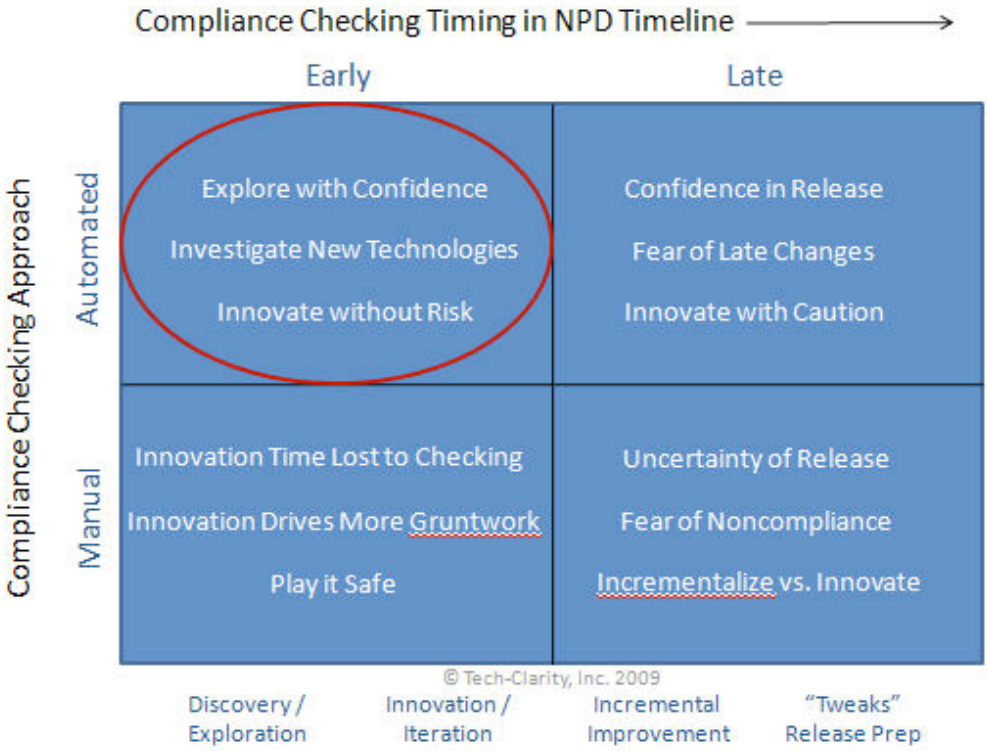

Figure 2: Impact of Automated Compliance Monitoring on Innovation

Digitizing Product Compliance Requirements

Compliance requirements come from many diverse sources, both external and internal, and may come from a host of regulatory bodies across the globe. Restrictions may be driven by legal concerns, marketing needs, company policy, or specifications from customers or large, multi-national retailers such as Wal-Mart. These requirements stem from legitimate customer concerns as well as legislation that is frequently driven by inflammatory press or as an overreaction to a public concern. Regulatory bodies are quick to enact restrictions and regulations, but painfully slow to standardize and consolidate with other regulators across geographical and political boundaries. Beyond the complexity from the varied sources and sheer number of regulations is the complexity of the regulations themselves. While some requirements are relatively simple maximum usage levels, many restrictions are far more complex. Regulations can vary by product category and usage in addition to country or region. The requirements are also dynamic, with new candidate substances controlled by REACH announced recently.

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The result is a complex matrix of regulations that must be considered. As companies strive towards the goal of developing and launching a single, global formula, the number and complexity of regulations becomes staggering. The regulations are difficult to track, let alone consider during an active product development or formulation effort. The formulator or chemist must simultaneously abide by a complex maze of mandates from different sources. The information is available, but typically not consolidated and easy to access. All of this is too much for individual chemists and formulators to understand and consider on an ongoing basis. It is simply not possible for a product developer to focus on creating breakthrough innovations while trying to consider every compliance issue of every material, there is just too much to consider when ingredients may bring in dozens of contaminants. This information needs to be translated into a set of automated business rules that can be used to flag potential problems before they happen. As Steve Doering from Revlon[1] explains, "*Automation keeps our business rules tight, where before everything was free-wheeling and formulas with issues got farther along in the process than they should have. Regulatory can add restrictions to raw materials in Enginuity, which helps chemists by letting them know right away instead of getting to the end and having to reformulate.*"

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Steve Doering, Database Administrator, Revlon[1]

Developing a Material Knowledge Base

Knowing the regulations is important, but if you don't have granular knowledge of your raw materials, design for compliance is a non-starter. Formulators and regulatory staff need to know what materials are approved for use in their company. This product intelligence helps contain cost, supporting ingredient standardization to enable greater purchasing power and reduce inventory. For cost containment purposes, a simple "approved" might be enough. For compliance, however, formulators need to know what sourced materials are composed of. It isn't enough to understand the material at a cursory level. To properly determine regulatory risk, companies can't stop at what is ideally in the materials, but also need to understand what trace contaminants can be in them on a supplier-by-supplier basis.

[1] See "About the Research" for more information on Revlon Consumer Products Corporation

"*A chemical is rarely one thing. We might know it has three items, but there are also stabilizers, trace contaminants, etc.*" explains Rushi Tasker, Vice President of R&D at Zotos [2]. "*With Enginuity, all of this information can be in one place, even though it's not a part of the formula, it's there off-label so you know what goes in. It is information we didn't have before for MSDS and registrations. Now toxicologists and others don't have to waste time digging to find what they need.*"

To provide the right material knowledge to formulators and establish the foundation for an efficient design for compliance process, companies must understand and capture ingredient knowledge in granular detail and make this available to formulators and other staff involved in the NPD process.

Know your Product and Formulas (at a Fundamental Level!)

Knowing what's in raw materials is a critical first step to determining product compliance. Perhaps it's an obvious statement, but companies also need to know the detailed composition of their finished products including stabilizers, trace contaminants, processing aids and other materials. Combining material information with current, accurate views of the formula including quantities, concentrations, and function of ingredients (active, solvent, antioxidant, emulsifier, stabilizer, etc.) is critical to evaluating and ensuring compliance. Companies need to understand their products at an extremely detailed level of chemical composition. This comes from an understanding of what ingredients are added to a batch, but also what will be left after processing. Processing aids, stabilizers and trace contaminants need to be considered in addition to raw materials.

Beyond the chemical composition, companies need commercial information about the product in order to assess compliance risk on a global level.

Beyond the chemical composition, companies need commercial information about the product in order to assess compliance risk on a global level. They must know the product in terms of marketing claims, intended markets, and intended use in order to determine compliance and registration requirements. Regulations such as Europe's 7th Amendment even vary based on usage instructions, for example where the product is intended to be left on the body or rinsed away after use. Capturing all of this information electronically is a key element required to automate the monitoring of products for compliance.

[2] See "About the Research" for more information on Zotos International (a division of Shiseido Co., Ltd.)

Design for Compliance: Pulling it all Together

If the formulator knows the regulations, the materials, the formulas, the FDA product category (under eye, sunscreen, etc.) and the intended market(s), all of the elements are in place to design the product for compliance. To streamline the process, the formulator's design tools should be able to pull chemical and commercial information together for the formulator so they don't spend their time searching for information in multiple sources.

To do this, compliance rules and product data have to be properly documented – and kept current – so they can be interrogated by the system. The formulas and raw materials should be analyzed, real time, against the rules to ensure compliance from the very beginning ("day one") of the product development process.

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Process automation can help by breaking down all materials to their fundamental composition, combining materials (such as methyl paraben) that are contributed multiple times from different raw materials, and then calculating overall formula quantities. Then, rules can be used to automatically assess formulas by adding up the contents of the ingredients, including potential contaminants. Effectively, the system should decompose each ingredient into its fundamental components and then reassemble them via the formula to develop a complete "bill of substance." This analysis serves as a guide to the formulator as they work, by providing immediate feedback to the chemist or formulator of potential issues. At the same time, the restrictions should not be so severe that they can't innovate and continue developing the product. Business rules should be added, however, that do not allow formulas to be released to the next step until any detected issues are resolved and company guidelines are met. Mr. Tasker from Zotos describes a system of this kind, "*In Enginuity, formulators get an alert – it goes red, shows an automatic flag - early in the development stage and they can't promote the formula. It provides a built in safeguard.*"

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Design tools can also develop region-specific ingredient labeling based on a range of product types so the chemist sees the impact of their decisions as the consumer would see them. In addition, the system should alert the formulator of any listings that would have to be put on the label which might be unattractive to consumers.

Automate Compliance Documentation and Registration

One of the major burdens on innovators and regulatory staff is developing regulatory documents. Product documentation is one of the biggest black holes for innovators' time, but documenting compliance is critical to getting products to market on a timely basis. Even if product development timelines can be compressed, if country-specific or region-specific product registrations are not completed it can hold up the entire launch of a product. The usual fire drill to create registration documents is inefficient, and even more importantly it pulls people away from developing the next product and slows future products down as well.

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Assembling regulatory documentation such as Product Information Packages (PIPs) is generally a significant challenge because it requires the assembly of data, specifications, structured reports, and documents authored by multiple groups. It must combine information stored as data and in documents (also known as "structured" and "unstructured" information). Pulling together the appropriate information in multiple formats and organizations is a challenge, and very time consuming. Different global locations require different information, and even different calculations, such as Canada's banding of ranges for raw materials. Automating the creation of these varied documents is difficult, but the resulting benefit to innovators is compelling. "*Automating MSDS and MLI is so useful to our chemists,*" says Steve Doering of Revlon, "*Automating MLI can take ingredient labeling from a 2 week process to 5 minutes at their computer.*"

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While it is mandatory to put the compliance information on paper, it is even better to have it in a content repository or database so it can be kept up to date and accessed electronically. Then, companies can use automation to get all of the different versions created effectively. Because of the dynamic nature of products and regulations, automated tools can produce an accurate, on-demand copy of the dossier. In this way, companies can stay up to date when a regulator requests a current product document in any of a number of required formats.

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Rush Tasker, Vice President R&D, Zotos

"*We have a very lean staff for regulatory because basic gruntwork filing is automated, so they can focus elsewhere.*" Rushi Tasker from Zotos says, "*With so much registration and filing, if I didn't have it automated via Enginuity, I would probably need to double my staff. The biggest problem with Product Information Packages is keeping them updated, it's virtually impossible to do manually – we would have to have people working on it full time.*"

Summary

Design for compliance helps companies bring innovative products to market rapidly on a global scale. If done correctly, it can allow formulators and chemists to spend more time on innovation. Key innovators can spend their time on developing products instead of looking up information to assure compliance or communicate to others for documentation. If done manually, compliance can be a large "hidden tax" on a company's innovators – severely limiting an organization's ability to innovate.

With the right level of automation and a framework based on regulatory and product knowledge intelligently applied at critical steps in the process, key innovators can spend less time manually reviewing and more time developing products that will capture the hearts – and the wallets – of consumers. Most importantly, if they don't have systems in place they will be much more conservative and won't try new things, they will be very incremental in their design and there won't be any major breakthroughs. Significant innovation requires the ability to explore new paths without feeling it's too risky. Without automated systems, formulators often retreat into a conservative approach. On the other hand, with confidence that a software-based compliance framework is monitoring product compliance for them in real-time, formulators and chemists are freed up to explore more new technologies and product forms that have the potential to yield the next blockbuster product.

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Recommendations

- Adopt a design for compliance process
- Develop a framework and implement intelligent software to capture requirements, raw materials, and formulas in a standardized and structured way
- Document regulatory requirements as electronic business rules
- Develop a raw material database with rich, granular knowledge of material composition
- Document products chemically (bill of substance) and commercially, including formulas, product categories, product type, and intended usage
- Implement systems that provide real-time analysis and feedback on compliance to the innovator from "day one" of the new product development process while they are exploring new options and have the flexibility to make changes
- Automatically inform the formulator or chemist of issues, providing guidance, but allowing them to continue working
- Do not allow for promotion of non-compliant formulations
- Automate creation of product registration documents, including product Material Safety Data Sheets (MSDS), Product Information Packages (PIPs), Qualitative Formula Reports, Quantitative Formula Reports, Country Specific Registration Documents and Formula Ingredients Statements/Master List of Ingredients (MLI)
- Implement a content repository that can handle both structured data and unstructured documents, with full change control, versioning and audit trails
- Look for a solution that is capable of automatically generating and dynamically updating product registration documents including complex Product Information Packages (PIPs)

About the Research

Tech-Clarity interviewed individuals from several leading cosmetic and personal care companies while conducting research for this paper. We would like to specifically thank Revlon Consumer Products Corporation and Zotos International Inc., a division of Shiseido Co., Ltd. for providing real-world examples of how formula-based companies are overcoming the challenges of product compliance through real-time, automated compliance monitoring. Both Revlon and Zotos are using Enginuity PLM software to manage product development and monitor product compliance.

About the Author

Jim Brown is the President and founder of Tech-Clarity, an independent research and consulting firm that specializes in analyzing the true business value of software technology and services. Jim has over 20 years of experience in application software for the manufacturing industries, with a broad background including roles in industry, management consulting, the software industry and research spanning enterprise applications such as PLM, ERP, SCM and others.

Jim is an experienced researcher, author and public speaker and enjoys the opportunity to speak at conferences or anywhere that he can engage with people that are passionate about improving business performance through software technology.

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