

TOEING THE LINE WITH CONFIDENCE

REGULATORY LABELING GUIDE: 6 BEST PRACTICES TO SUSTAIN COMPLIANCE

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ENTERPRISE LABELING SOLUTIONS



A DIFFICULT BALANCING ACT

Managing regulatory compliance has always been a challenge for organizations, particularly those in the Chemical, Life Sciences and Food & Beverage industries. The stakes are even higher today as companies must balance adherence to strict—often exhaustive, always changing—policies and procedures with the desire to embrace digital transformation and accelerate business to keep up with growing global competition.

This leaves the regulatory affairs as well as quality and compliance personnel in the middle, serving as the conduit between standards bodies or agencies and senior leadership representing manufacturing, supply chain and other key operational functions. The back-and-forth can be dizzying as one side expects compliance at all costs and the other desires getting product to customers faster and more efficiently than ever.

Labeling is one such area that crosses departmental boundaries. For manufacturing and supply chain, the barcode label is the passport that enables the fast identification, transport, tracking and delivery of product—from production line to end customer. For the regulatory manager, that same label must conform to myriad regulations and standards, many of which are a moving target due to constant change.



CONSIDER THE LABELING REGULATIONS IN THESE INDUSTRIES

In Chemicals, the Globally Harmonized System (GHS) of classifying and labeling chemicals mandates that pictograms with red triangles, hazard statements, signal words and more appear on applicable finished goods as well as the variety of drums, cartons and containers shipped across the supply chain. Country-specific regulations for the import/export of chemicals add even more complexity.

In Medical Device, many companies in the US are still grappling with the FDA's Unique Device Identification (UDI) system for registering and labeling products. Now they must contend with global requirements like the EU's impending Medical Device Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR), which have their own labeling stipulations.

In Pharma, as part of the FDA's Drug Supply Chain Security Act (DSCSA) manufacturers must comply with serialized product labeling to ensure full traceability from production to patient. Similarly, drug makers that do business in Europe will have to comply with the Falsified Medicines Directive (FMD) when that goes into effect in 2019.

In Food & Beverage, the FDA's Food Safety Modernization Act (FSMA) expects full transparency of how products are made and where they are at all times in the distribution and consumption layer—and labels must support that effort as well. Of course, the nutrition label itself must adhere to an array of regulations to provide consumers with the information they need to make safer, more informed decisions.

MANAGING GLOBAL STANDARDS, EMERGING MARKETS



In addition to complying with these strict, industry-focused regulations, companies must also pay attention to global standards and regional-specific requirements. This gets particularly complicated as you enter emerging markets where countries like Brazil, China and India, as well as growing economies in Africa, continue to set unique label requirements for their trade partners. As such, regulatory departments must be more vigilant than ever in keeping up with evolving standards.

Growing role of GS1. GS1 is one of the world's largest organizations that develops and maintains standards to enable trade partners—manufacturers, suppliers, distributors and retailers—to use a common language as products traverse from one party to the next. With more than a million members in over 100 countries, GS1 provides, among other things, unique numbering and identification systems as well as barcodes that are captured on labels to help improve visibility and traceability across the international supply chain.

Increasingly GS1 standards are being recognized and accepted to support regulatory compliance. For example, in the U.S. GS1 meets the FDA's criteria for issuing Unique Device Identifiers (UDIs) and associated barcodes to support patient safety and supply chain security. As a result, you'll often find regulatory and compliance



departments reviewing GS1 data and barcodes to ensure that their company—and their partners—are properly following standards.

Unique rules by country. Management of regulations and standards gets especially tricky as you expand operations into other regions of the world. Many countries expect you to meet their strict requirements for language, symbologies, transactional data and other criteria. The reasons for these stipulations are valid—as they improve the speed and efficiency in how products move through the supply chain—but they also present their own set of challenges. For instance, in Russia, medical devices must not only be in the local language but now also include special registered markings and data from their ruling body.

THE PERILS AND PITFALLS OF NON-COMPLIANCE



The risks associated with non-compliant labeling vary, but all are damaging, if not potentially crippling…

Health and safety issues. First and foremost, you never want to put lives in danger due to mislabeling. Unfortunately, there are too many horror stories in recent years in which products were labeled incorrectly resulting in sickness and even death. Whether it was allergen omissions on food labels or the infiltration of counterfeit drugs with inaccurate labels, the losses are tragic and usually lead to lengthy, costly lawsuits.

Product recalls. When food, chemicals and drugs are mislabeled, companies typically have to go through an exhaustive recall process, which takes up valuable resources, throws off production schedules and greatly reduces profitability. Most companies have recall procedures in place—but that doesn't mitigate the significant impact to operations.

Fines and penalties. Regulatory agencies like the FDA warn violators of fines (upwards of $500K or more), seizures, suspension or revocation of licenses and criminal sanctions including imprisonment. While there's been a bit of a grace period allowing companies to get their processes in place for recent regulations like UDI and GHS, you can be sure agencies will be looking to crack down on violations in the coming months.

Supply chain disruption. A ripple effect of unforeseen events like product recalls or seizures is the interruption to the flow of goods across your supply chain. What if product is confiscated



or even destroyed when crossing international borders? That's what happens in China if your chemicals are mislabeled. Not only does this impact your bottom line, but it can hurt relationships with customers and trade partners and lead to additional fines.

Damaged brand/reputation. Beyond health risks as well as costly fine and delays, non-compliant labels—and the negative publicity they generate—can have a lasting effect on a company's brand, which is sometimes irreversible. This situation creates opportunity for competitors and can jeopardize a company's future.

NAVIGATING AND SUSTAINING COMPLIANCE: 6 LABELING BEST PRACTICES



Challenged with managing global regulations—and facing the consequences of non-compliance—now's a good time for organizations to rethink their current labeling processes. Even though regulatory and compliance teams from different industries have different rules to follow, there are some common labeling practices that can be adopted and applied across all enterprises.

Indeed, new advancements in Enterprise Labeling take these best practices to another level in helping regulatory teams not just sustain compliance but save time, improve collaboration and drive overall efficiency across their supply chain.

STANDARDIZE AND CENTRALIZE LABELING—ONCE AND FOR ALL

Standardizing on a single labeling solution certainly isn't a new concept, but for large organizations dealing with complex regulations, it just doesn't make sense to rely on disparate, disconnected labeling solutions. When you isolate labeling to the production lines at remote sites, it's hard to ensure label accuracy and brand consistency across the organization. Plus, you greatly limit the visibility into labeling for key stakeholders at corporate.

Today's powerful, enterprise-class labeling solutions make standardization a practical, viable reality. And when you can centralize control of labeling and provide secure access to regulatory, quality and other functions within the organization, you can systematically



manage the design, review and printing of labels—whether product, packaging or shipping labels—across all your facilities. You also reduce the number of templates you need to store. Plus, new cloud-based capabilities make it easy to extend labeling to contract manufacturers, co-packers, suppliers and distributors.

Bonus tip: The advent of new "'multi-site" deployment capabilities provide added flexibility by empowering businesses to control label data and make decisions centrally while also allowing remote facilities to operate the labeling function autonomously.

INTEGRATE WITH SOURCES OF TRUTH

Accuracy is paramount in regulatory labeling but with laws changing and evolving, particularly in global markets, it can be hard to stay current. That's why it's critical to integrate labeling directly with your source of compliance data. Continuing to rely on spreadsheets or "file drop" approaches to manage labeling data is asking for trouble. For example, as rules change like in the EU for Medical Device labeling, you can have confidence that once new product ID numbers are captured in your regulatory database, they will be reflected on the label. Today's Enterprise Labeling Solutions offer reliable integration with a host of applications and systems including ERP, MES, PLM and LIMS.

Bonus tip: When looking to tie your labeling to larger, more complex systems like those from SAP or Oracle, don't underestimate the value of certified integrations. This provides added peace of mind that your labeling solution has been tested and approved for use in these mission-critical environments.

OWN YOUR PART OF THE LABEL—LITERALLY

In many organizations, regulatory and compliance teams are often reliant on IT to manage label design and updates. You may ultimately be responsible for what's on the label, but any significant changes have to go through a cumbersome, time-consuming coding process. Instead, why not simply manage your part of the label? New layering capabilities let different groups own and control their portion of the label. As part of the regulatory team, you can now add requisite pictograms, symbologies, safety information, etc. and apply it to the appropriate labels. This not only streamlines approvals but supports mass updates to appropriate labels to ensure accuracy and consistency.



Bonus tip: Make sure labeling tools are intuitive and easy to use. Look for a WYSIWYG interface that lets you view labels with real data and see what it looks like before going to print. Also drag & drop rules creation lets regulatory departments configure the logic that pertains to their specific labels—including what templates receive a certain warning hazard or language change.

CREATE A "CLOSED LOOP" WORKFLOW AND APPROVAL PROCESS

With so many people involved with labeling, it's critical to have a systematic workflow process to make sure no one is left out—especially regulatory personnel. The manual or disconnected approaches of the past create too many cycles and increase the risk of errors and mislabeling. Fortunately, today's Enterprise Labeling Solutions can automate workflow to streamline the review and approval of labels, content and artwork, helping to ensure that the right people are included. You can also manage version control and easily apply user rules based on role and department. This is key in regulated industries where validation, traceability and compliance are essential.



Bonus tip: Look for solutions where workflows are easily configurable to match your way of doing business. For industries like Med Device and Pharma, it's also important that the workflow support e-signatures for 21 CFR Part 11 compliance.

GAIN CRITICAL INSIGHT FOR AUDITING AND REPORTING

With labeling regulations continuing to increase and evolve, it's important that companies are able to quickly monitor, track and capture labeling activity—right down to the label, printer and users. Who knows when governing bodies like the FDA will audit your

operation? Now you can leverage built-in business intelligence to pull data and create customized reports that address a wide range of regulatory requirements in a validated environment.

**Bonus tip:** Interactive dashboards are now available that go beyond simply reporting and provide real-time status of labels, workflows, print requests, configurations and user actions—from creation and approval to publication and print. Now both labeling professionals and auditors have assurance that processes are operating in accordance with key performance indicators as well as strict regulatory guidelines. Real-time insight also helps organizations make faster, more informed decisions to improve labeling.

SCALE EASILY TO ENTER—AND COMPLY WITH—NEW MARKETS

As companies look to enter new and emerging markets, they must contend with unique and country-specific regulatory requirements. A centralized approach to labeling helps organizations be more proactive in designating resources and aligning with new requirements, such as localized languages that must go on the label. Today's most advanced Enterprise Labeling Solutions support more than 10 languages out of the box with the tools to add and modify languages as needed.

**Bonus tip:** When you leverage built-in business logic found in enterprise-class labeling solutions, you have limitless flexibility to support a wide range of label variability including regional languages, symbols, and customer-specific requirements. Again, this logic can be applied without complicated coding and IT involvement.

To quickly recap, evolving regulatory requirements certainly put a burden on your labeling process—regardless of your industry. And the risk is just too great to rely on traditional methods of labeling. Fortunately, new innovations in Enterprise Labeling are making it faster and easier to sustain compliance while driving significant operational gains across your global supply chain.

Strike a balance with your key stakeholders and achieve regulatory compliance with greater ease.

LEARN MORE

To find out more about the latest developments in Regulatory Labeling, visit **loftware.com** or check out our **blog** devoted to labeling issues that affect your business in an ever-changing global economy.

Loftware, Inc. is the global market leader in Enterprise Labeling Solutions with more than 5,000 customers in over 100 countries. Offering the industry's most comprehensive labeling solution, Loftware's enterprise software integrates SAP®, Oracle® and other enterprise applications to produce mission-critical barcode labels, documents, and RFID Smart tags across the supply chain. Loftware's design, native print, and built-in business rules functionality drives topline revenue, increases customer satisfaction, and maximizes supply chain efficiency for customers. With over 30 years of industry leadership, Loftware's Enterprise Labeling Solutions and best practices enable leading companies to meet their customer-specific and regulatory requirements with unprecedented speed and agility.

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