UNLOCK THE POWER OF LABELING TO GAIN STRATEGIC EDGE

ENTERPRISE LABELING FOR THE PHARMACEUTICAL INDUSTRY

LOFTWARE™
ENTERPRISE LABELING SOLUTIONS

INDUSTRY REPORT

IT'S TIME FOR POWERFUL NEW SOLUTIONS IN PHARMACEUTICAL LABELING

For the pharmaceutical industry, the focus is on patient safety and improved patient outcomes. It's also on driving greater efficiencies, cost reductions, and collaboration with contract manufacturers throughout the supply chain. In this environment, labeling is growing in importance, and there are a number of reasons why.

REGULATORY REQUIREMENTS

In a world of complexity and regulation, few industries are as complex and regulated as pharmaceuticals. Standards for quality, safety, and procedural accuracy are exceedingly high–as are the stakes–and failure to meet these standards can have profound consequences, including loss of life.

The global nature of the pharmaceutical industry–with worldwide manufacture and markets–means that regulations are growing around the globe. In addition, the GS1 System of Standards is aimed at improving supply chain efficiencies in numerous industries, including pharmaceuticals, and these standards are continuously evolving.

In the United States, the Food and Drug Administration (FDA) has broad jurisdiction over pharmaceutical shipments crossing US borders, as well as within the country. For the FDA, labeling violations are the easiest violations to find. They require no site inspections, no product testing. Mislabeled shipments - where the label is not correct for a variety of reasons - often result in refusal and/or return of product as well as hefty customs fines. The FDA also has labeling-related guidelines for GxP (Good x Practices) for the pharmaceutical industry that should be followed. The Code of Federal Regulations for Electronic Records and Electronic Signatures, or 21 CFR Part 11, has been set forth as guidance for some time, but now the electronics transactional data and eSignatures either are or will be required.

The regulation that is greatly impacting pharmaceutical labeling in the US is Title II of the Drug Quality and Security Act (DQSA), the Drug Supply Chain Security Act (DSCSA). The goal of DSCSA is to create a system that can trace drugs throughout the supply chain so that legitimate products can be verified, illegitimate products detected, and drug product recalls facilitated. Provisions covered under DSCSA cover the full supply chain: manufacturers, wholesaler drug distributers, repackagers, and dispensers. In an ongoing rollout, the following elements will be part of the comprehensive track and trace plan: product identification, tracing, and verification; detection and response; notification; wholesaler licensing; and third-party logistics. All stakeholders will share responsibility for securing the pharmaceutical supply chain to protect providers and patients, and to guard against mishandling of products through counterfeiting, gray marketing, and diversion.

A WIDELY DISPERSED SUPPLY CHAIN

Beyond satisfying regulatory requirements, there are a number of other challenges in the pharmaceutical world – challenges that can be met through better labeling. The pharmaceutical supply chain is highly complex, with many steps, as ingredients are often shipped in bulk, repackaged and reshipped, before they find their way to the manufacturer producing the branded end-products. Multiple tiers of wholesalers are often involved. Oftentimes, borders are crossed. Labeling is essential to the smooth flow of the pharmaceutical supply chain, where problems can arise at any juncture in the chain, or may "wait" to become manifest only in a finished product.

COMPETITIVE PRESSURES

Within the pharmaceutical industry, global competition is fierce, and competitive pressures – as well as pressures from health care providers and insurers to keep costs from skyrocketing – result in an increasing focus on maintaining costs and on operational efficiency. Here, the right labeling approach can yield big dividends.

MARKET EXPANSION

Entering new markets is essential for success–they're where many of the opportunities for growth are–but each new market presents unique challenges–and unique labeling needs, as pharmaceutical companies must satisfy local language, shipping, and regulatory demands.

TAKING A STRATEGIC PERSPECTIVE ON LABELING

In this world of complexity and regulation, labeling must be viewed from a systemic perspective. Yesterday's approach to labeling, often done on an operational and departmental level, with insufficient strategic planning for organization-wide standards or policies, has resulted in a disparate, piecemeal labeling "solution" that's expensive, inefficient, and error-prone. Mislabeled shipments, if the labels aren't corrected within a short period of time, are rejected, or languish in customs. Fines may be levied. Lost or faulty product shipments can't be tracked, putting pharmaceutical firms at risk. The labeling requirements of trading partners and customers can't be easily met. Opportunities to reinforce brand are missed.

Today, forward-thinking global pharmaceutical companies increasingly want to look at labeling from a strategic, systemic perspective. They recognize that labeling is a critical mechanism for maintaining compliance, ensuring brand consistency, improving operational efficiency, and supporting business growth.

WHAT HAPPENS IN THE ABSENCE OF A STRATEGIC LABELING PROCESS

Failure to treat labeling as a strategic process can prove costly. Without a strategic approach to labeling, a pharmaceutical company is likely to experience:

EXCESSIVE REGULATORY COSTS

Pharmaceutical companies must comply with specific regulatory requirements in each market where their products are sold. New intended uses for a drug must be indicated on labels. This may mean label changes multiple times each year – changes that must be understood, designed, approved and implemented. Failure to rapidly respond to regulatory changes results in supply disruptions, lost revenue, and customs fines.

INEFFICIENT ACCESS TO CRITICAL LABEL DATA

Pharmaceutical companies have invested heavily in enterprise-wide business systems. Yet device and packaging labels are often created using disparate processes that aren't integrated automatically to sources of truth residing in key data repositories. The resultant errors, redundancies, inefficiencies and mislabeling can significantly impact the bottom line.

LOCAL LABELING INEFFICIENCIES

In today's global supply chains, product design, manufacturing and packaging processes occur in multiple locations around the world. In the past, label design, control, approval, and printing were driven locally. While localities were able to comply with regional requirements, the variety of labeling solutions and systems that resulted often lacked accuracy and were operationally inefficient. This hampered a manufacturer's ability to meet broader market requirements in a timely manner, increasing the risk of supply chain disruption due to regulatory action. It also meant that when a local labeling system was down, production would shut down as well.

INCONSISTENT BRANDING

Brands convey expertise, innovation, breadth of care, safety, and concern for the patient. Disjointed labeling processes make it challenging to consistently apply branding guidelines and standards to globally manufactured and distributed products. This can translate into lost sales, increased regulatory scrutiny, delayed entry into new markets – and even place patient safety at risk. With the wrong approach to labeling, for instance, it's difficult (and perhaps even impossible) to track down recalled product batches.

CASE IN POINT

IMPROVING LABELING EFFICIENCY AND ACCURACY BY REPLACING A TIME-CONSUMING, ERROR-PRONE MANUAL PROCESS

With over 4,000 employees in 50 countries, and with product distribution in 100 countries worldwide, this pharmaceutical company has a complex manufacturing and distribution network. The company recognized that labeling is a critical component of their process. The inability to identify products can have security, health, and financial impacts. The company printed multiple labels for a wide range of needs: pallet, loading unit, shipping box, QA/QC, etc. Any new label design was a major challenge, and modifications to existing labels required a huge effort.
The company is in the process of implementing a global ERP system (Oracle), and chose the opportunity to deploy an enterprise labeling solution.

TAPPING BUSINESS RULES AND DRAWING ON A SINGLE SOURCE OF TRUTH

This pharmaceutical manufacturer looked to Loftware to meet their labeling needs. With Loftware, they have been able to:

- Create a single source of truth by integrating with Oracle ERP system
- Automate a largely manual process, saving time and effort
- Reduce label development times by empowering business users to easily make required changes, without IT support
- Use sophisticated business rules to drive more consistent and accurate label production
- Easily scale labeling as their business grows
- Keep track of templates and template changes for regulatory purposes

They are also now able to use labeling to help investigate when something has gone wrong in their supply chain.

ACHIEVING STRATEGIC GOALS WITH LOFTWARE'S ENTERPRISE LABELING SOLUTIONS

By treating labeling as a strategic process – and by implementing an enterprise labeling solution – pharmaceutical companies are able to achieve consistent branding, reduce regulatory costs, eliminate data redundancy, and improve overall labeling efficiencies. Loftware Enterprise Labeling Solutions provide a new level of visibility and control for validated label management. Pharmaceutical manufacturers can enjoy these benefits:

SINGLE SOURCES OF TRUTH LABELING REDUCES COSTS AND ERRORS

Pharmaceutical companies have invested heavily in enterprise systems that contain single sources of truth for managing their business and reporting to regulators. Unlike legacy labeling solutions that maintain off-line data sources (often relying on manual data entry or the use of individual productivity tools like spreadsheets) and increase the risk of mislabeling, Loftware sources label data directly from single sources of truth, i.e., from key data repositories, ERP systems, and other applications, utilizing business rules in its processes. Data replication and synchronization costs and complexity are reduced or eliminated.

INTEGRATED LABEL PROCESSES PROMOTE QUALITY AND EFFICIENCY

When labeling is integrated with the enterprise business processes, as well as with an existing authoring solution, rather than existing in a stand-alone system, processes are simplified and non-value added activities are reduced. Loftware enables operators to perform their value-added manufacturing, packaging, and distribution tasks without having to access separate labeling systems or worry about keeping labeling synchronized with process or operational data. Loftware software applies business rules to operational data to automatically determine the right label format, content and device based on the context of the business transaction.

DATA- AND RULES-DRIVEN LABELING ENABLES RAPID RESPONSE TO CHANGING REGULATIONS

Loftware enables pharmaceutical companies to rapidly respond to changing regional and international regulatory requirements for labeling, including those being established by DSCSA. By leveraging a built-in business rules engine, companies can support labeling variations using configurable rules in a controlled manner, removing the risk of manual errors and mislabeling. Using data-driven label content and configurable business rules provides the flexibility to address requirements quickly while minimizing validation and approval activities necessary to implement those label changes into production.

CASE IN POINT

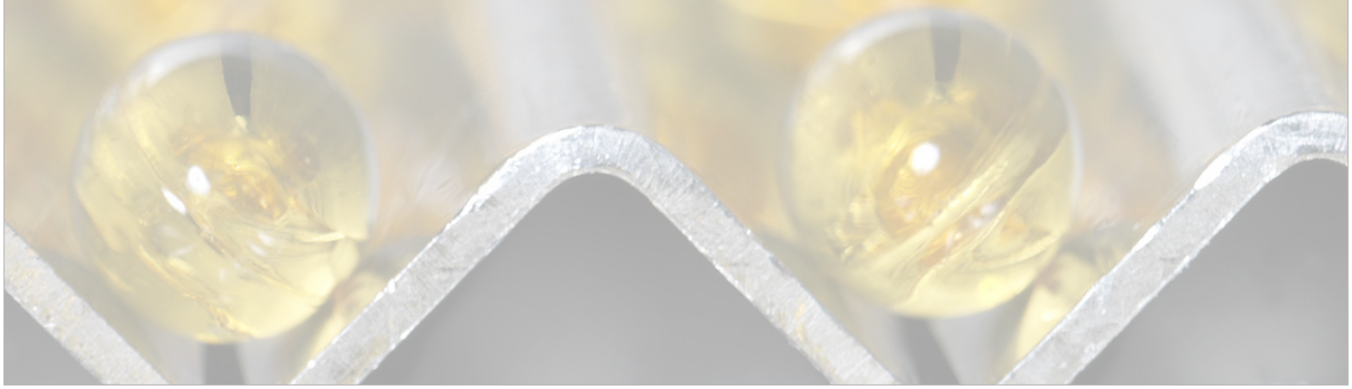
REDUCING TCO, WHILE IMPROVING ACCURACY AND EFFICIENCY WITH LOFTWARE

As a major division of one of the world's foremost pharmaceutical companies, this manufacturer understands that labeling plays a critical role throughout the supply chain (manufacturers, labs, warehouses, etc.) and that without labeling, manufacturing stops. The company deals with many different label types–incoming materials, weigh-dispense, WIP, sampling labels, shipper box, pallets, finished goods–which have different layout and data requirements. While specific requirements may differ, there is a consistent requirement for standardization and consistency, and reliance on accurate source data. The company recognized that using multiple disparate labeling approaches was costly to support, challenging to manage, and difficult to adapt to changes. With a goal of simplifying their labeling landscape, and reducing the Total Cost of Ownership (TCO) for labeling, this pharmaceutical manufacturer decided to implement an enterprise-wide labeling solution.

With Loftware Enterprise Labeling, this pharmaceutical company is able to:

- Minimize TCO by centralizing labeling and enabling sharing across sites
- Increase label accuracy and quality by integrating with SAP and creating a single source of truth
- Meet various labeling requirements through use of business rules
- Adapt to expanding and future needs with a scalable solution
- Reduce regulatory burden with GxP compliance company-wide
- Eliminate manufacturing downtime with high-availability labeling architecture

…and are avoiding the risks associated with the use of legacy systems (in-house and old installs), including the risk of those with knowledge of those systems leaving the company.



DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) IMPLEMENTATION PLAN

In 2013, the Drug Quality and Security Act (DQSA) was signed into law. Title II of the DQSA, the Drug Supply Chain Security Act, is aimed at creating an electronic, interoperable system that will be able to identify and trace certain prescription drugs distributed within the US. Track and trace regulations will cover over 70% of pharma by 2017. The implementation timeframes extend over a 10-year period.

FLEXIBLE APPROACH HELPS MEET CUSTOMER-SPECIFIC REQUIREMENTS

Organizations within the pharmaceutical supply chain are increasingly required to respond to their customer and partner labeling demands. These requirements are varied: logo placement or other branding demands, language variations, location-specific information, country-specific regulations, parts labeling that conforms to a customer's existing systems, labeling that enables health care providers to better monitor patient care and help them achieve faster reimbursements and more. With Loftware, pharmaceutical manufacturers are able to quickly respond to customers' requirements, reducing what was once a month-long process to a matter of a few days.

EASY-TO-USE INTERFACE EMPOWERS BUSINESS USERS

In the pharmaceutical industry, frequent label changes are a matter of course. New regulations emerge with increasing frequency. Additional intended uses must be reflected in labeling. Mislabeled shipments languish in customs. Entering new markets means accommodating new languages and country-specific rules. Customers or supply chain partners make requests that they'd like to see rapidly met. Branding guidelines are updated. With Loftware Enterprise Labeling, non-technical business users can quickly make label changes. This both speeds up the labeling process–and reduces demand on scarce IT resources.

ENTERPRISE LABEL PRINTING SUPPORTS THE GLOBAL ENTERPRISE

Loftware's Enterprise Labeling Solutions enable pharmaceutical companies to produce labels anywhere in the global landscape – labels based on approved templates and using common labeling infrastructure. With an enterprise approach, pharmaceutical companies can ensure consistency by controlling label content and format including layout, graphics, text and barcodes. In addition to labeling, corporate branding guidelines can be deployed with minimal time and IT involvement. With Loftware, product labels will project a global brand image regardless of where products are manufactured, packaged or sold.

A MISSION-CRITICAL PROCESS DEMANDS A MISSION-CRITICAL SOLUTION

Across the pharmaceutical industry landscape, labeling is increasingly recognized as a mission-critical process that helps further an organization's strategic goals. First and foremost: meeting exacting regulatory compliance standards. This means a labeling solution that supports labeling that is GS1, DSCSA, and 21 CFR Part 11 compliant. In addition to offering labeling that helps ensure compliance, a labeling solution should be able to stand up to audit demands.

Beyond regulation, pharmaceutical companies require a labeling solution that's standardized and centralized, and taps into the data and business rules of existing enterprise systems. Such a solution enables organizations to become more operationally efficient – saving on costs, avoiding expensive mistakes, and ensuring that even the most remote facility is in compliance with governmental and industry regulations, while also meeting overall internal branding standards.

That's why some of the world's foremost pharmaceutical manufacturers rely on Loftware to help them take a strategic approach to labeling.

See how Loftware can provide you a competitive edge to stay compliant while improving the bottom line. **Visit** www.loftware.com **and keep up with the latest industry news by subscribing to our** Blog.

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Loftware, Inc. (www.loftware.com) 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 25 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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