

ENTERPRISE LABELING FOR THE MEDICAL DEVICE INDUSTRY



STAY COMPLIANT WHILE IMPROVING SUPPLY CHAIN OPERATIONS



IT'S TIME FOR POWERFUL NEW SOLUTIONS IN MEDICAL DEVICE LABELING

For medical device manufacturers, 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 medical devices. 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. Labeling is central to compliance with regulations.

Within its Quality Systems regulation, the US Food and Drug Administration (FDA) has Code of Federal Regulations (CFR) labeling-related requirements that must be followed in order to meet Current Good Manufacturing Practice (CGMP).

Some FDA labeling regulations are specific to medical devices, but there are also more general requirements such as regulations governing electronic products, sterilization methods, and the labeling of products containing natural rubber/latex.

With a goal of improving patient safety, the FDA is also phasing in a unique device identifier (UDI) system that will enable medical devices to be identified throughout the entire distribution and use cycle. UDI requirements, which address issues such as traceability, are impacting both US companies and multinationals that market in the US.

Another key regulation of the FDA that can help streamline workflow for medical device companies is the use of electronic signatures in place of paper records and handwritten signatures. Compliance with 21 CFR Part 11 within labeling operations can further reduce complexity, manage audit trails, and boost productivity.

When it comes to regulatory compliance, labeling matters.

A WIDELY DISPERSED SUPPLY CHAIN

Another challenge facing the medical device world—and one that can be solved through better labeling—is the fact that today's supply chains are widely dispersed. Labeling is essential to the smooth flow of the medical device supply chain, where problems can arise at any juncture in the chain, or may "wait" to manifest in a finished product.

COMPETITIVE PRESSURES

For medical device makers, 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 reside. But each new market presents unique challenges and unique labeling needs, as medical device 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 strategic perspective. Yesterday's approach to labeling, often done on an operational and departmental level, with little attention paid to standards or policies, has resulted in a disparate, piecemeal labeling "solution" that's expensive, inefficient, and error-prone. Shipments are rejected, or languish in customs. Lost or—worse—faulty product shipments can't be tracked, putting device manufacturers at risk. Opportunities to reinforce brand are missed.

Today, global medical device companies increasingly look at labeling from a strategic 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 medical device company will experience:

EXCESSIVE REGULATORY COSTS

Medical device companies must comply with specific regulatory requirements in each market where their products are sold. This may mean label changes multiple times each year with changes that must be understood, designed, approved and implemented. Failure to rapidly respond to regulatory changes results in supply disruptions and lost revenue.

CONFLICTING LABEL DATA

Medical device manufacturers have invested heavily in enterprise-wide business systems. Yet device and packaging labels are often created using disparate processes and data that aren't integrated with a company's core system. Thus, they aren't drawing on data that is the single source of truth. (Nor are they able to tap the business rules laid out in an enterprise system.) The resultant errors, inefficiencies and mislabeling can significantly impact the bottom line.

LOCAL LABELING INEFFICIENCIES

In today's global supply chains, product design, manufacturing and packaging processes happen around the world. In the past, label design, control, approval and printing were driven locally. While they adapted to regional restrictions,

CASE IN POINT

ACHIEVING UDI COMPLIANCE ENABLES A EUROPEAN MANUFACTURER TO MARKET THEIR PRODUCTS IN THE US

When it comes to orthopedic, urological, and dental prophylaxis devices, this European-based manufacturer is a market leader with a global distribution network. The US is an important market for them, so certification from the Food & Drug Administration is essential. As the date for the first phase of the FDA's Unique Device Identification system neared (UDI), they recognized the need for a labeling process that would enable them to meet the FDA mandate. Their existing labeling approach lacked support for the symbologies required for UDI. Further, the existing solution relied on error-prone manual data entry, resulting in costly mislabeling, and print speed issues were impacting production.

Meeting UDI requirements, improving quality and speeding up production with Loftware

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

- Use business logic as their platform for handling UDI and other regulations
- Obtain FDA certification to continue selling in the US
- Provide traceability for all of their products
- Improve label quality by using data from the company's ERP system, a "single source of truth"
- Substantially decrease print time to less than one second.

the variety of labeling solutions and systems that resulted often lacked accuracy and were operationally inefficient. This hampered a manufacturer's ability to meet 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.

INTEGRATED LABEL PROCESSES PROMOTE QUALITY AND EFFICIENCY

When labeling is integrated into the enterprise business process, 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 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 medical device companies to rapidly respond to changing regional and international regulatory requirements for labeling, including those mandated by the FDA's Unique Device Identifier systems. 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. For example, companies can now configure more streamlined approval workflows and eSignatures within their Loftware labeling solution in a validated, 21 CFR part 11-compliant environment.

FLEXIBLE APPROACH HELPS MEET CUSTOMER-SPECIFIC/PRIVATE LABEL REQUIREMENTS

Organizations within the medical device 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

ELIMINATING SITE-SPECIFIC LABELING BUILDS OPERATIONAL EFFICIENCY

For nearly 50 years, this medical device maker has been dedicated to developing innovative products that better patient outcomes, and to improving the operational processes that facilitate this. Several years ago, they identified a significant operational problem: a site-specific labeling approach at facilities throughout the United States, as well as in Central America and France.

In scrutinizing this approach, the company discovered that they had a number of redundant data repositories outside of their Oracle ERP. Some sites used Access, others used Excel, and there were many discrepancies between Oracle and these satellite databases. Sites also relied on manual data entry that was highly susceptible to human error. The label printing process was manual as well, with labeling templates selected manually during production, and data flows that were poorly documented. The resulting operational inefficiencies were costly.

Eliminating data redundancy and improving operational efficiency with Loftware

When this device maker began working with Loftware, they were quickly able to replace their piece-parts approach to labeling with a unified, enterprise-wide solution that tapped their Oracle ERP as the single source of truth. Error-prone manual data entry and multiple sources of disparate data have been eliminated. To help meet government regulations, and best practices, Loftware supports a number of industry standards, including ISO, ANSI 3182, EDI, GS 1128 barcoding, static G10 barcoding – and is helping this company as they adopt the Unique Device Identifier (UDI) standards now being phased in by the FDA.

With Loftware, this medical device maker is able to:

- Eliminate data redundancy
- Reduce downtime
- Speed up problem resolution, especially in the area of data reconciliation
- Minimize customer returns
- Decrease rework and relabeling

They're also better able to support their business messaging and branding initiatives, and meet new and evolving regulations in a growing market for them.

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. With Loftware, medical device manufacturers are able to quickly respond to customers' requirements, reducing what was once a month-long process or longer to a matter of a few days.

ENTERPRISE LABEL PRINTING SUPPORTS THE GLOBAL ENTERPRISE

Loftware's Enterprise Labeling Solutions enable medical device companies to produce labels anywhere in the global landscape – labels based on approved templates and using common labeling infrastructure.

With an enterprise approach, medical device 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 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 medical device 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 CGMP-compliance, along with supporting other countries' regulatory demands, including those in newer export/import markets where standards are emerging and continually evolving. In addition to offering labeling that helps ensure compliance, a labeling solution should be able to stand up to regulatory audit demands.

Beyond regulation, medical device makers require a labeling solution that's standardized and centralized when necessary, and that 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 medical device 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](#).**



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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