

OPTIMIZE TRACEABILITY

6 Best Practices in Packaging and Labeling
to Improve Supply Chain Integrity

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New Market Opportunities Bring New Risks

Manufacturing across multiple industries is back on the rise. Much of this growth is due to emerging economies in places like China, India, Brazil and even countries in Africa where demand is soaring for a range of products—from electronics and pharmaceuticals to food and consumer goods. For manufacturers, this brave new world creates opportunity while it expands and diversifies the supply chain, both upstream and downstream.

Of course, as you widen your scope and bring on new trading partners, you also introduce new risks. Depending on who you're doing business with and where, can you be sure materials are sourced from a trusted supplier? Does your offshore distributor have the security to prevent cheaper gray market goods from being sold in place of yours? If an incident does occur with your product, how quickly and effectively can you implement a recall and identify the root cause of the issue?

Consider These Challenges Across Key Industries

In pharma counterfeit drugs have become a worldwide epidemic where falsified drugs enter the market through the Internet and less secure channels. Not only does this take away business and erode customers' trust of reputable brands but, more importantly, could cause a health hazard to consumers and you may be held responsible.

In food and beverage there are countless stories of tainted or contaminated product reaching consumers resulting in sickness and even death. Manufacturers need to be able to track down and recall affected product as well as pinpoint where the contamination occurred. Brand is also negatively impacted.

In electronics counterfeiting remains a prevalent and costly issue as inferior or "knock-off" components find their way into finished goods, creating safety and health hazards and, again, holding the manufacturer liable. Customer trust is difficult to win back when this occurs.

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In chemicals, where profit margins are already slim, manufacturers are always looking for more affordable suppliers, but in the process, may be sacrificing quality standards. As a result, materials may be compromised and adversely affect finished product. Responsibility will fall on manufacturers to trace the source and remedy the situation.

In medical device patient safety is paramount and, as such, requires fast detection of any device malfunction including the ability to trace back the design and development of a product. Also referred to as “materials vigilance,” this means pulling the device off market before anyone gets hurt.

What is Traceability?

As companies expand their supply chain to include new partners and new regions, they need better visibility to ensure quality and react faster to events—from fake or falsified goods to accidental incidents that impact customer safety, brand loyalty or overall profitability. That’s where traceability comes into play to essentially become the risk management solution.

But when people talk about traceability, many confuse it with tracking, which is only part of the equation. Tracking refers to following the movement of product from one place to the next, and the activity surrounding that transaction. For example, you may follow a certain part from supplier to manufacturer while documenting touch points for inventory management or logistical purposes.

Tracing is all about identifying a product’s origin—including the parts or materials used in making it—through records, data capture and labeling across the supply chain. You may capture the specific unit or batch of a product, which may include certificates of origin, PO numbers, lot numbers—all of which can be used to link back to the source.

Combined with tracking, traceability essentially provides a full audit trail of a product from its parts/materials/ingredients to its manufacturing and distribution to the end user or customer. The better your traceability, the faster you can respond to costly disruptions of all kinds across your supply chain.

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Regulations Pushing Traceability, Too

There are regulations now in place that require traceability measures. In pharmaceuticals, for example, both the US and EU have traceability requirements in the form of serialization. In the food & beverage industry, the US Food & Drug Administration's (FDA) Food Safety Modernization Act (FSMA) has put added pressure on manufacturers to adopt traceability tools to follow all ingredients from farm to fork. This is more important than ever as under the FSMA, the FDA now has the authority to order a mandatory recall. More effective supply chain traceability enables manufacturers to ensure FSMA compliance while reducing the risk of recalls of any kind.

While most often associated with pharmaceuticals and the FDA's Drug Supply Chain Security Act (DSCSA), serialization has also been adopted in other industries like electronics and is very similar to the Unique Device Identification (UDI) system used in the medical device space. It's the process by which

products are marked with a unique identifier—typically a unique number or alphanumeric code—and is implemented to enhance supply chain security. The unique serial number, along with other related information, is typically encoded in a barcode that can be read electronically.

It's important to note that serialization on its own provides virtually no benefit to the supply chain, rather, it is the use of that serialized data in today's traceability systems—as well as in packaging and labeling—that enhances supply chain security.

Consequences of Limited Traceability

The risks associated with poor traceability of your product vary, but all are damaging, if not potentially crippling.

Health and safety issues

First and foremost, you never want to put lives in danger. Unfortunately, there are too many horror stories in recent years in which products were

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either contaminated or had flawed parts resulting in sickness, injury 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.

Lengthy, costly recalls

When food, chemicals, devices and drugs are compromised, 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 without adequate traceability, it can have a significant, negative impact on operations, brand image, market share, etc.

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 without requisite traceability. While there's been a bit of

a grace period allowing companies to get their processes in place for regulations like FSMA, you can be sure agencies will be looking to crack down on violators 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 lost or redirected when crossing international borders? This not only affects your bottom line, but 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, product recalls—and the bad publicity they generate—can have a lasting effect on a company's brand equity, which is sometimes irreversible. This situation creates opportunity for competitors and can jeopardize a company's future.

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Leveraging Standards to Improve Communication, Visibility

Enabling more effective, whole-chain traceability involves linking technology platforms and systems between supply chain partners using a common, global language or standards. Standards enable companies to talk to one another through the identification encoded in barcodes. By using the same standards to identify and capture data about products, partners can share specific product information more efficiently and accurately, which ultimately benefits both businesses and consumers.

GS1 is a global champion of standards that empowers companies to uniquely identify products in the supply chain to optimize visibility, as well as overcome limitations of proprietary solutions and systems.

By using GS1 identification numbers like the Global Trade Item Number® (GTIN®), companies can identify products as well as supplementary data (e.g., expiration date, batch/lot number) to further drive transactions when

a barcode is scanned. Manufacturers and their trade partners that have visibility based on these GS1 standards improve traceability knowing the exact attributes and location of each product.

Of course, standards are only part of the story; the processes and systems that leverage standards must also be robust, scalable and integrated to fully support traceability.

That's where supply chain labeling and artwork management can play an integral role in not only enhancing the visibility of your extended supply chain, but also driving significant efficiencies in the form of reduced costs, greater agility and faster time to market.

6 Best Practices in Labeling and Artwork Management

Challenged with an ever-expanding supply chain—and the many risks associated with it—now's a good time for organizations to reevaluate existing processes and see where improvements can be made.

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While labeling and artwork management are viewed as essential functions, they are often overlooked as a source of real value and efficiency. Times are changing and today's enterprise-class solutions offer capabilities to not just help optimize traceability but benefit your overall business.

Unify, centralize labeling and artwork management

Traditionally, labeling and artwork management solutions have been siloed across an organization, resulting in duplication of efforts, poor communication and costly disruptions. And yet, there are common requirements between the two functions, including the sharing of similar content as well as the review and approval among many stakeholders.

Bonus tip: *Implementing a centralized labeling and artwork management solution is easier than ever thanks to flexible deployment options. Choose cloud, on-premise or a hybrid model with the versatility to support labeling, artwork management or both—depending on your specific needs. You can even deploy the solution as a managed service, greatly reducing the burden and cost on your infrastructure and IT staff.*

Today, there is increasing realization that by deploying these two solutions together via one centralized platform, companies can tear down barriers, improve accuracy, shorten approval cycles and meet go-to-market goals. An equally important benefit of this convergence is that companies immediately improve the visibility of labels and artwork from design and revisions to final printing and delivery—the same labels and artwork that go on your finished goods and are tracked across your supply chain.

Integrate with sources of truth, ensure data accuracy

When you can seamlessly integrate labeling and artwork management with existing applications and business processes, you can ensure accuracy while maintaining your “way of working.” Accuracy is paramount in traceability as you rely on that labeling and packaging data to follow the progression of product from development and manufacturing to distribution throughout your supply chain channels. Continuing to rely on spreadsheets or “file drop” approaches to manage data is just asking for trouble as you can easily deviate from critical specifications.

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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 package and label. Today's 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 and artwork management 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 solution has been tested and approved for use in these mission-critical environments.

Create a “closed loop” workflow and approval process

With so many people involved in the labeling and artwork management process—not to mention the sheer amount of content—it's critical to have a systematic workflow to tie it all together. The manual or disconnected approaches of the past create too many cycles and increase the risk of errors and delays. Fortunately, today's labeling and artwork management solutions

can automate workflow to streamline review and approval, ensuring that the right people are included. Secure, centralized repositories for managing imagery, phrases, GS1 barcodes, logos and more are also available. Plus, you can 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 Medical Device and Pharma, it's also important that the workflow support e-signatures for 21 CFR Part 11 compliance.

Extend your process to trusted trade partners

As you open up your trade channels and work with more suppliers, distributors, co-packers, 3PLs and others, it becomes critical to bring them into your own processes. Thanks to role-based access where you can assign a wide range of user privileges, you can integrate partners easily and securely. Create the labels for all your inbound materials and have your supplier

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print them locally. You'll be able to see orders being built and track their progress—from the carton and pallet level to the truck they're arriving on. Same thing goes for your finished goods sent to distributors and resellers. View, manage and track all the artwork, all the labels, all the data to know where product is at all times.

Bonus tip: *When you can dictate what goes on the labels for inbound materials, you can not only better trace supplies from the source, you eliminate relabeling and reduce lead time. This means you can reduce inventory and warehouse space—ultimately saving you millions in operating and capital costs.*

Gain real-time insight to keep product on track

With traceability requirements continuing to increase and evolve, it's important that companies monitor, track and capture labeling and packaging artwork activity—right down to where it is, who's viewing it and what changes are being made. Who knows when governing bodies like the FDA will come knocking to audit your operation? Now you can leverage built-in

business intelligence to pull real-time data and create customized reports that address a wide range of regulatory demands in a validated environment. In the unfortunate event that a recall is required, you can respond much faster using the same platform to communicate to stakeholders—including trade partners—and take swift action.

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 labeling and packaging professionals 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 that may even prevent mass recalls.*

Scale easily to enter and monitor—new markets

When entering new and emerging markets, you must contend with unique and country-specific regulatory requirements. A centralized approach to labeling and artwork management helps

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organizations be more proactive in designating resources and aligning with new requirements, such as localized languages that must go on the label and artwork. Today's advanced solutions support more than 10 languages out of the box with the tools to add and modify languages as needed. This gives you peace of mind that your product will get through customs, comply with regional requirements and remain in your purview until its final destination.

Bonus tip: When you leverage built-in business logic found in enterprise-class labeling and artwork management solutions, you have limitless flexibility to support a wide range of variability including regional languages, symbols, and customer-specific requirements. This logic can be applied without complicated coding and IT involvement, helping to further simplify your traceability efforts.

In Conclusion

To quickly recap, new and emerging economies are creating opportunities for manufacturers across several key industries. But with these opportunities come risk and the need to improve traceability of product across the extended supply chain. Fortunately, new innovations in Enterprise Labeling and Artwork Management bring an unprecedented level of visibility and control to enhance your track-and-trace initiatives while reducing costs, enhancing collaboration and shortening time to market.

Learn More

To find out more about the latest developments in Enterprise Labeling and Artwork Management, visit loftware.com or check out our [blog](#) educating about challenges similar to traceability that affect your business in an ever-changing global economy.

Loftware is the global market leader in Enterprise Labeling and Artwork Management solutions with more than 5,000 customers in over 100 countries. Offering the industry's most comprehensive digital platform, with SaaS, cloud-based and on-premise solutions, Loftware redefines how enterprises create, manage and print complex labeling and packaging artwork and scale across their operations. Loftware solutions integrate with SAP®, Oracle® and other enterprise applications to produce mission-critical barcode labels, documents, RFID smart tags and packaging artwork. Our combined platform – whether for labeling, artwork management or both – enables customers to uniquely meet regulatory mandates, mitigate risk, reduce complexity, ensure traceability, improve time to market and optimize costs as they meet customer-specific, brand, regional and regulatory requirements with unprecedented speed and agility.



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