



# 6 vital questions on pharmaceutical labeling

Interview with Laura Johnson, Life Sciences  
Industry Specialist, Software



# How does cloud labeling help pharmaceutical companies **compete in global markets?**

This Q&A addresses key challenges that companies face and provides insight into the significant gains that could be realized using the right cloud-based labeling and packaging solution.

Labeling is complex; today's pharmaceutical organizations are faced with a range of evolving requirements that complicate the process and leave many companies accepting outside changes and regulatory updates to the process as a cost of doing business. But it doesn't have to be. Labeling can make a huge difference, enabling IT and supply chain decision makers to overcome challenges, and provide their company with a distinct competitive advantage.

Read on to get an expert's insight into how the right solution can deliver significant, measurable results for you.



# Our supply chain is a beast to manage. How can cloud labeling and packaging improve efficiency?

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 suppliers and wholesalers are often involved. Oftentimes, borders are crossed. Labeling is essential to smooth the 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.

A centralized approach allows companies to integrate the labeling process with their existing ERP, PLM, or other validated environments to drive data from “sources of truth,” which offers greater control. By using a central database, companies can avoid the need to replicate data, which reduces errors and offers improved labeling consistency for deployment to other plants and distribution partners internationally. This ultimately provides a new level of consistency, simplifies troubleshooting, and streamlines labeling, helping to drive greater supply chain efficiency.

When labeling and packaging are integrated with the enterprise business processes rather than in a stand-alone system, processes are simplified and non-value-added activities, such as regulatory updates, are reduced.



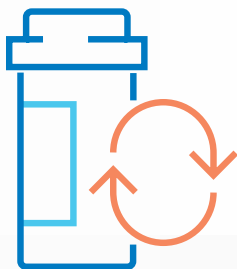
## **What about compliance with regulations such as the FDA'S DSCSA?**

### **What makes one labeling solution better than another?**

The global nature of the pharmaceutical industry, with worldwide manufacturing and markets, means that complex regulations are constantly growing and changing. 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 US, the Drug Supply Chain Security Act (DSCSA) is designed to create a system that can trace pharmaceuticals throughout the supply chain so that legitimate products can be verified, illegitimate products detected, and product recalls facilitated. The provisions of the DSCSA cover all parties in the supply chain, including manufacturers, wholesaler drug distributors, re-packagers, and dispensers. All stakeholders 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 cloud labeling solution enables pharmaceutical companies to rapidly respond to changing regional and international regulatory requirements for labeling, including those being established by the 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 label changes into production.



In addition to compliance with the DSCSA, there is also the FDA's Title 21 of the Code of Federal Regulations (CFR) Part 11, which provides guidance for electronic records and eSignatures to streamline workflows. Here again, a cloud labeling solution offering workflow and eSignature capabilities can provide a new level of visibility and control for managing labels in the highly regulated pharmaceutical industry.



## How can cloud labeling help me deal with constant change?

Organizations within the pharmaceutical supply chain are increasingly required to respond to their customer and partner labeling and packaging demands. These requirements are varied: 2D and linear barcodes, serialization, updated regulatory symbols, logo placement or other branding demands, language variations, location-specific information, country-specific regulations, labeling that enables healthcare providers to better monitor patient care and more. With cloud labeling, pharmaceutical manufacturers can quickly respond to customers' requirements, reducing what was once a month-long process to a matter of a few days.

One company in the pharmaceutical/chemical space relied heavily on orders obtained through their webpage. The issue was that the formulations could change frequently but their labeling system wouldn't always reflect the changes in time for shipment, causing a major issue with their customers. They had struggled with this issue for years.

With a cloud labeling solution in place, they were able to change the data for their product, which automatically changed the label in real time. Standard labels, templates, and systems allow for global compliance and a single source of the truth for change management.

Labeling is essential to smooth the flow within the drug supply chain, where problems can arise at any juncture. How quickly and accurately companies respond to customer requests or meet changing regulatory requirements, such as the DSCSA, can mean a huge difference in time-to-market, customer satisfaction, and cost savings.



## Cost reduction is paramount. How will labeling deliver measurable savings?

In a survey conducted with about 200 manufacturing professionals, including many from the pharmaceutical industry, nearly half (47 percent) indicated they were experiencing costly downtime due to labeling disruptions. The reasons cited for these delays included dealing with customer-specific labels, product-specific labels, and

slow label printing speeds, in that order. When you add up all these isolated labeling issues occurring across different segments of your supply chain, you're looking at hundreds of thousands of dollars of lost productivity, severely impacting your bottom line.

One pharmaceutical company we have worked with had the same issue, managing several different label types — incoming materials, weigh-dispense, WIP, sampling labels, shipper box, pallets, finished goods — all of which have different layout and data requirements. With a goal of simplifying the labeling landscape and reducing the Total Cost of Ownership (TCO) for labeling, this manufacturer leveraged a centralized solution to pull data from trusted resources, improve accuracy, and consolidate and share templates across multiple sites. More importantly, they achieved their ultimate goal of simplifying their global labeling process and lowering overall costs.



Additionally, an automated, cloud-based process allows companies to achieve significant printing performance gains, allowing labeling to keep up with production. With this type of labeling platform pharmaceutical companies can initiate print jobs and produce labels anywhere in the global landscape. Labels are based on approved templates, using a common labeling infrastructure.





## How can cloud labeling create efficiencies **at the supplier level?**

For years, companies in the pharmaceutical industry have struggled with how they integrate partners into their processes. Today many companies use third parties as extensions of their own business. When it comes to labeling, companies handle third parties in multiple ways — but historically it's been a manual process wrought with inefficiencies and difficult to manage consistently at remote locations. Many manufacturers rely on third party printing companies to produce and ship the labels directly to the partner or they pay to have the labels printed by an outside vendor after receipt of an order. These options can be extremely costly and can cause significant delays and mistakes, especially when you need to take into account ongoing regulations. The best way to handle this challenge is to integrate third parties into cloud labeling and packaging solutions.

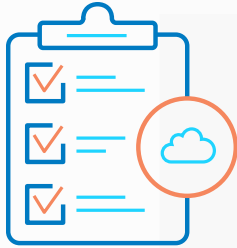
Using a secure partner portal or a secure cloud labeling system, pharmaceutical manufacturers can allow suppliers to access and print labels locally — with the right information expected by the receiving organization.



Globally consistent labeling and packaging reduces the need to manually ship labels around the world and eliminates the need to relabel inbound shipments, saving time, labor, and money while reducing the likelihood of errors.

Companies can set up this solution in a secure environment so third parties access information, labels, and the printers only they are supposed to see. Many of our customers leverage this ability to print their labels at third-party sites around the world and have improved their processes immensely while saving millions of dollars in relabeling and reducing preprinted label inventory.





## Need to know more? What are your critical questions about labeling?

Learn more about how cloud labeling solutions can help your pharmaceutical organization comply with regulations, reduce costs, and drive greater efficiencies across your extended supply chain. Visit [Loftware's website](#) for more information or [contact one of our experts](#).



## The world's largest cloud-based labeling and artwork management provider

No matter what the challenge – digital transformation, time to market, or brand authenticity – Loftware can help you make your mark. We understand how global supply chains work and know that each item you produce, and ship is an expression of your company's brand. We can help you improve accuracy, traceability, and compliance while improving the quality, speed, and efficiency of your labeling. Our end-to-end cloud-based labeling platform helps businesses of all sizes manage labeling across their operations and supply chain and our solutions are used to print over 51 billion labels every year. Loftware also fosters supply chain agility and supports evolving customer and regulatory requirements, helping companies save over \$200 million in fines annually. And with over 500 industry experts and 1,000 global partners, Loftware maintains a global presence with offices in the US, UK, Germany, Slovenia, China, and Singapore making us a trusted partner for companies in automotive, chemicals, clinical trials, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail/apparel and more.

### Locations worldwide:

- US
- Germany
- UK
- Slovenia
- Singapore