



Demand these 6 things from your pharmaceutical label supplier

The November 2018 DSCSA serialization enforcement deadline is now in the rearview. But with a recent report showing that [75% of cases fall short of requirements](#) and more DSCSA compliance deadlines on the horizon for trading partners up and down the pharmaceutical supply chain, 2019 will be a busy year.

The last thing pharmaceutical companies should worry about is a failure of suppliers to meet their critical quality requirements. And according to [a survey from the Food and Drug Administration \(FDA\)](#), label mix-ups accounted for 11% of packaging and labeling (P&L) recall events in 2014. In 2019 —with your attention focused on implementing serialization on your own lines— there's no time to handle such label quality mishaps.

Beyond a [full portfolio of standard and specialty labeling capabilities](#), here's what pharmaceutical manufacturers should expect from their label suppliers:

1. Complete traceability of each label throughout the manufacturing process — from raw material to the label products being inspected and applied on their production lines.
2. Confidence that each pallet of labels will arrive at their manufacturing plant exactly as it left

- the label supplier's facility, with secure tamper-evident pallet wrap.
3. Each label produced exactly to their approved specifications by means of PDF scanning, vision systems and documented quality procedures and work instructions.
 4. Complete documentation, including all of the reports and information needed for quality and regulatory compliance purposes — personalized to each organization's unique needs.
 5. A no-downtime disaster recovery plan to ensure they always get the labels they need, as well as flexible scheduling and platforms to prevent missed deadlines and drug shortages.
 6. Knowledge that their label supplier prioritizes the analysis, prevention and reduction of risk throughout the entirety of their process.

In this article, we'll discuss each of the above deliverables you should expect from your [pharmaceutical label manufacturer](#), offering tangible examples of how to identify a label supplier who provides each. And with a vendor who can provide you with complete confidence in every label, every time, you can focus your attention on other critical areas of your manufacturing process.

Complete traceability of each label throughout their facility

If there's ever a label issue in the field, you should be able to call your label supplier with the product code and purchase order number and have them trace the labels back through their facility to the specific raw material order used to produce the labels. Not only will this level of traceability help to find the source of the problem, but it will also aid in identifying other labels or orders that could likewise be suspect.

To illustrate the importance of traceability, let's narrow in on a specific example. One of our large pharmaceutical clients called us with a potential recall in the field related to their labels, giving us the purchase order number and product code for the labels in question.

We searched through our detailed records of each label we printed for them in our comprehensive enterprise resource planning (ERP) system, and determined the labels weren't printed at our facility. Using the information we provided them, our client was able to ascertain that the labels in question were actually printed at their secondary label supplier's facility, which subsequently helped identify other affected labels.

We determined the source of the problem and narrowed down the pool of potentially affected labels. Although the labels had not been produced at our facility, we were able to help deter a potential field recall.

We have a robust ERP system that allows for 100% traceability of every order and raw material that passes through our facility. The moment we receive a shipment of raw materials, we immediately scan and enter the rolls into our system. Once an order is received from a pharmaceutical client, we allocate rolls to that specific job, so that all raw material is completely traceable throughout the process.

Tamper-proof delivery of your labels to prevent counterfeiting

[\\$46 billion in lost profits](#). That's what counterfeit drugs cost the pharmaceutical industry each year, not to mention the risk the black market poses to patients. We know this. It's why we shrink wrap every pallet with extremely aggressive banding before shipping it to our client's facility — which has to be cut through to open the pallet. This makes it apparent if any pallet of labels has been tampered with and gives you the peace of mind that you've received every label you've ordered, exactly as it was when it left our facility.

Printing each label, exactly to your specifications

In any industry, the quality and consistency of your labels is of utmost concern. However, in the pharmaceutical industry, if a speck of dust is on the printing plate it may cause a decimal point to be out of place, and that's more than an issue of quality — it's a matter of consumer safety.

That's why we use a PDF comparator to scan first piece samples and compare them to the customer-approved proofs. Our vision system compares labels to the approved template to catch any potential quality defects or print-to-die registration issues.

Customizing documentation of compliance information to your needs

Many label providers offer a standardized certificate of compliance, but each pharmaceutical product is different. And each pharmaceutical manufacturer requires different documentation from their label supplier depending on what's required by the FDA or their customers.

We gather and submit required quality and regulatory documentation in a format customized to each client's needs. We'll sit down with new customers, determine the information that needs to be gathered and build it into our ERP system. Any required reports can be automatically generated and printed with all subsequent orders.

A no-downtime disaster recovery plan to ensure you always get the labels you need

Your pharmaceutical labeling supplier should have a plan in place to ensure you receive your label orders —and your customers receive their medicine— without delay and without exception.

In addition to raw material inventory on site, we have an agreement with our suppliers guaranteeing two-day delivery on our orders. And with facilities located throughout North America with similar production lines, we're able to respond flexibly to fluctuating demand and potential disasters.

Weaving risk analysis and reduction into their every process

ISO 13485:2016, the latest iteration of the standard for quality management systems in the pharmaceutical and medical industries, focuses on risk-based decision making. Your

pharmaceutical labeling manufacturer must move beyond a reactive approach to quality management. Rather, they need to conduct risk analysis and reduction activities at their facility on a regular basis.

That's why we regularly perform internal audits and mock recalls to ensure our process works seamlessly, minimizing risk and providing high-quality labels for every customer, every time. And we welcome on-site press approvals, customer visits and audits to allow you to monitor and evaluate our process in person.

We proactively track quality issues, establish trends and determine risk-reducing solutions. When we identify an issue or trend, we analyze whether there's a solution that all of our customers could benefit from. It's our robust quality system and proactive approach to risk reduction that helped us earn our ISO 13485 re-certification.

With years of experience delivering labels for the largest pharmaceutical manufacturers, we can handle the tightest lead times, strictest quality standards and deliver even the most complex label solutions. And we're committed to delivering every label you order exactly as you envision. [Start a conversation with our team about your pharmaceutical labeling needs.](#)