



6 critical questions and answers on medical device labeling

Interview with Laura Johnson, Life Sciences Industry Specialist, Software



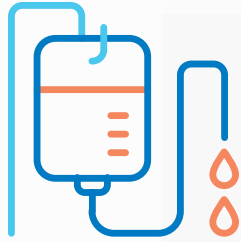
6 critical questions and answers on medical device labeling.

How can you leverage innovation in cloud labeling to help your medical device company succeed in a highly regulated, highly competitive global marketplace?

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

Labeling is complex; today's medical device manufacturers are faced with a range of evolving requirements that complicate the process and leave many organizations accepting this process as the 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 for an expert's insight into how the right labeling solution can deliver significant, measurable results for you.



Our supply chain is a beast to manage. How can labeling improve efficiency?

The medical device supply chain is more complex than ever before. Internal teams such as packaging, quality and regulatory are playing an increased role. You also need to manage third parties like suppliers, distributors, and providers all while trying to comply with regulations and keep products moving swiftly across the ecosystem. Each step along the way requires powerful, reliable labeling to ensure efficient and precise tracking of medical goods, while also supporting a wide range of requirements, including barcodes, multiple languages, regulatory symbols, and more.

A centralized cloud-based approach to labeling allows companies to integrate labeling processes with existing ERP, PLM, or other validated environments to drive data from “sources of truth”, offering greater accuracy and control. By leveraging a central data store, companies can avoid the need to replicate data or manage a separate database, which minimizes overhead, reduces errors, and offers improved labeling consistency for utilization at other plants and distribution

partners internationally. This provides a new level of consistency, simplifies troubleshooting, and streamlines labeling, helping to drive greater supply chain efficiency.



What about compliance with regulations? **What makes one labeling solution better than another?**

Adhering to regulations that define how products are developed, marketed, shipped, and disposed of is essential to avoid fines, retain customers, enter new markets, and in some cases, stay in business. Labeling continues to play a crucial role in meeting evolving standards, especially those like the FDA's Unique Device Identification (UDI) and the European Union's Medical Device Regulation (EU MDR) requirements where labeling and identifying parts and packages is critical for patient's safety.

There is actually a silver lining to these global standards going into effect: a label containing necessary information about a product can be leveraged as it moves through the supply chain. Individualized labels can contain important information as to how the product was made, what it contains, how it should be handled, and how it should be disposed of.

In fact, one of the best ways to achieve a sustainable, extendable program is to implement a cloud labeling solution, which integrates production labeling and business processes to support mission-critical labeling. This dynamic and data-driven approach allows businesses to react to evolving customer, regional, and most importantly, regulatory requirements. This approach also ensures consistency across a global supply chain, enabling companies to meet performance and scalability requirements with the flexibility to sustain complex, high volume labeling requirements.



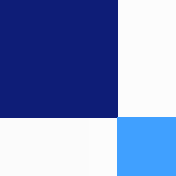
In addition, there is also the FDA's Title 21 of the Code of Federal Regulations (CFR) Part 11, which provides guidance for electronic records and eSignatures to streamline workflows. Here again, a cloud labeling solution should support workflow and eSignature capabilities to provide a new level of visibility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



How can cloud labeling help me deal with constant change?

The impact of change is significant to the medical device business. When it comes to labeling, constant change, be it complying with regulatory mandates or managing customer-specific label changes, can mean a manual, slow, labor-intensive process. If you rely on multiple, non-standardized labeling products, this often leads to an array of disjointed, often redundant templates created in silos which slows production and delays shipments. And because changes are not always captured earlier upstream in the process, there will be risk of errors and inconsistencies.

With a standardized, centralized cloud labeling solution, companies can make changes at the data source, whether it's in the ERP, MES, or other system, and ensure that they will be reflected on the appropriate labels. Change it once, apply it many times. And when you can provide access to the same cloud labeling solution to multiple users at various locations, you have full visibility and control across the value chain.



Labeling and packaging are essential to smooth the flow within the medical device supply chain, where problems can arise at any juncture, or may “wait” to manifest in a finished product. How quickly and accurately companies respond to customer requests or meet changing regulatory requirements can mean a huge difference in time-to-market, customer satisfaction, and cost savings.



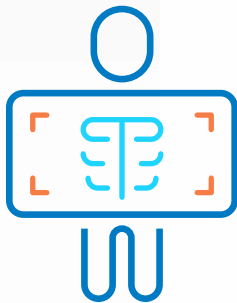
Cost reduction is paramount. How will cloud labeling deliver measurable savings?

In a survey we conducted with about 200 manufacturing professionals (including many from the medical device industry), nearly half — 47% — 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 are looking at hundreds of thousands of dollars of lost productivity, severely impacting on your bottom line.

As mentioned, a cloud labeling solution, tightly integrated with existing systems, unifies your entire labeling and packaging process. By gaining centralized visibility and control, you can better adapt to changing requirements. Errors are reduced because you're pulling data from sources of truth, be it SAP, Oracle, your PLM system, etc. Any customer specific label changes that come in are handled systematically with secure access to a library of templates that can be updated as needed — while greatly reducing the number of templates you need to manage. In fact, one of our medical device customers was able to go from 10,000 templates to a mere 20 templates supporting the entire organization.

Additionally, this automated process allows companies to achieve significant printing performance gains, allowing labeling to keep up with production. With this type of labeling platform, medical device companies can initiate print jobs and produce labels anywhere in the global landscape. Labels are based on approved templates, using a common labeling infrastructure. Another customer was able to centralize deployment of labeling and execute print jobs faster than ever, going from several minutes in many cases to under six seconds across the enterprise.





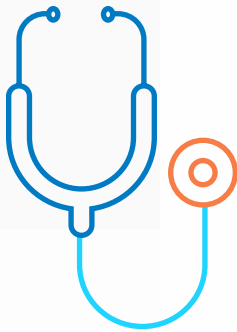
How can cloud labeling create efficiencies **at the supplier level?**

For years, companies in the medical device industry have struggled with how they integrate partners like suppliers, contract manufacturers, and distributors into their processes. Today many companies use third parties as extensions of their own business. When it comes to labeling and packaging, companies handle third parties in multiple ways — but it's commonly been a manual process with great difficulty. Many manufacturers still package and ship the labels right to the partner or they pay to have the labels printed for the third party by an outside vendor. These options can be extremely costly and can cause significant delays and mistakes, especially when you need to consider ongoing global regulations. The best way to handle this challenge is to integrate the third parties into a cloud labeling solution.

Using either their existing partner portal or a secure cloud labeling system, medical device manufacturers can allow suppliers to securely access and print labels locally — with the right information expected by the receiving organization. Globally consistent labeling reduces the

need to manually ship labels around the globe or to relabel inbound shipments at the point of receiving, saving time and money while reducing the likelihood of errors.

Companies can set up this solution in a secure environment so third parties only see information, labels, and printers they are supposed to see. Many of Loftware's 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 inventory reduction.



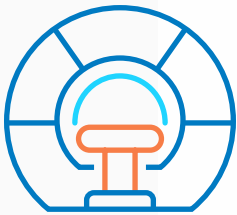
How can cloud labeling help us as we **grow and expand our business?**

Market expansion is essential for success and even survival. The faster you can satisfy local regulatory, language, and shipping demands with your labels, the faster you can drive revenue. When a specific regulation changes in a country where you are doing business, can you make the necessary text changes to labels

quickly without stopping the manufacturing line? We discussed the value of pulling data from sources of truth like SAP or Oracle, but a change like this may require programming which can take four to six weeks to complete.

To overcome this challenge, look for cloud labeling with built-in business logic that can be dynamically updated as needed without having to wait for changes or updates to your application. Business rules can be configured within a standard user interface to update label specifications quickly and dynamically — be it language, branding, or regional compliance where they're needed.

For example, suppose you bring on a new distributor in Germany who wants to introduce your medical device right away to meet a huge customer opportunity. With configurable business logic as part of the labeling solution, select users can quickly pull up the template, translate the text to German, and add appropriate symbols and health & safety language without any delays. Product gets out the door within days versus weeks or months.





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

Learn more about how cloud labeling solutions can help your medical device business comply with regulations, reduce costs, and drive greater efficiencies across your extended supply chain. Visit <https://www.loftware.com/solutions/industries/medical-device>.



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.

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