

7 Key Challenges of Pharmaceutical Labeling


And how to overcome them



Executive Summary

The number of challenges for the global pharmaceutical industry is perhaps higher than ever before. Competitive pressures, new stipulations from governments and regulators, products coming off patent and market pricing pressures have combined: pharmaceutical companies are increasingly obliged to seek competitive advantage through efficiency and cost reduction measures.

Among the available options, labeling technology offers many opportunities for pharmaceutical companies to successfully tackle rising challenges, as this report demonstrates.



A typical wish list for a major pharmaceutical company would be to:

- Align and harmonize label requirements
- Establish ownership and governance for label content, including creation and maintenance of layouts, outside the company's IT department
- Reduce the number of label layouts, particularly redundant layouts due to different systems
- Transition from paper-based labeling catalogs to digital document management systems
- Reduce the amount of development required to a minimum
- Split data and design modeling
- Enable compliance with increasing regulatory requirements
- Minimize the need for relabeling


In this report, we set out seven current challenges for the pharmaceutical industry, together with proposed solutions that will help companies to understand labeling in the context of these challenges.

The potential impact from straightforward changes in labeling processes may be surprising to many in the industry.

1. Data Integration

Rising demand for fast response times in manufacturing has prompted the pharmaceutical sector to implement new data integration processes. Chief among them is integrating Manufacturing Execution Software (MES) and Enterprise Resource Planning (ERP) systems with an Enterprise Labeling approach.

Pharmaceutical companies have long seen the need to integrate labeling with their MES and ERP systems; however, most have hard coded labels inside these systems, a practice that requires extensive IT development and maintenance resources. A cloud-based labeling solution enables a pharmaceutical company to integrate labels with the master data, digitize the entire label creation process and empower business users to handle change requests.



This type of data integration enables pharmaceutical companies to address a number of label management issues, including:

- Reducing labeling complexity
- Avoiding costly set-up and downtime
- Consolidating the number of templates
- Reducing risks from label data and mislabeling errors
- Streamlining label design, approval, maintenance and support processes
- Maintaining regulatory approvals (such as from the FDA and EU regulators)
- Ensuring label and brand consistency

A cloud-based labeling solution also prevents the creation of data silos – or reduces them if they already exist – so that pharmaceutical companies can rely on a ‘single source of truth’ for their labeling needs.

By digitizing label information and eliminating paper-based catalogs, business users can access a company’s entire label library from one interface. They can quickly locate and compare labels across all of their operational locations, searching not only based on label names but also content, and get instant query results. Users can search all text fields, variables, fonts and barcodes across all of their label storage. Business users can also more easily compare and identify differences between label variations and revisions, thus improving accuracy and template consolidation.

Summary

A cloud-based labeling solution enables organizations to consolidate and avoid redundant label development and maintenance tasks, moving the responsibility for these areas from specialist developers to the general business user. This organizational transformation prevents inconsistency, eliminates latency and achieves new levels of quality control, label data accuracy and template consolidation.



2. Regulatory Compliance


For pharmaceutical companies, regulatory compliance is a part of doing business. Government regulations such as FDA CFR 21 part II, Eudralex Annex 11 and GAMP 5 require companies to ensure the security and accuracy of their electronic records, as well as prove compliance with GMP. In addition to having to comply with governmental authorities, pharmaceutical companies also have to submit to audits from business partners and customers. Failure to comply with or meet the standards of any of these requirements can have catastrophic consequences for a pharmaceutical company's business and reputation.

With a legacy approach to labeling, meeting federal or international requirements often required a lot of manual overhead and paperwork. Adopting a cloud-based labeling approach and digitizing label storage reduces manual processes, improves label quality and streamlines compliance procedures. A cloud-based labeling solution does this by enabling centralization, label lifecycle management and audit trails.

Pharmaceutical companies that have implemented a cloud-based labeling approach have found that their data quality has improved, and the time and effort spent on compliance have reduced dramatically. This is achieved through consolidating existing label files into a series of intelligent universal templates, which, in turn, dramatically simplifies label management and reduces the number of change requests.

Having one solution for all of a pharmaceutical company's labeling and direct marking also aids its compliance with regulations by keeping all relevant data in one place so that track and trace is far easier to achieve.

The FDA itself has moved from requiring paper evidence, with its vulnerability to human error, to electronic methods of validation using computer technology to ensure safety and security. The best modern labeling solutions now allow companies to demonstrate who printed a label, which label was printed, and which printer the job was sent to, while tracking exactly when each step occurred. These systems allow business users to design, review, approve and control label data from a document management system, providing approvals, time stamps, maintenance of records and electronic signature capture.



Implementing a cloud-based labeling solution also places pharmaceutical companies in the best position to respond to future requirements, such as serialization. Increasingly, each pack of tablets, each bottle of medicine and each box of any pharmaceutical product will have a unique serial number, enabling it to be tracked and traced. This is partly an anti-counterfeiting measure and also assists in improving safety and accountability in the industry.

By using one labeling solution for both labeling and direct marking printers, pharmaceutical companies will be able to meet the demands serialization will place on their business. Through printing barcodes for individual boxes, cases, pallets or any other pharmaceutical packaging, regulatory requirements can be fulfilled and products tracked and traced.

Summary


To ensure that a pharmaceutical company is fully compliant with relevant regulations, future-proofed against likely new developments, safeguarded against action from regulators, able to demonstrate traceability and in line with current best practice, it is vital to adopt an Enterprise Labeling approach which can fulfill these criteria and protect the organization.

3. Maintaining Safety Standards

One of the main goals behind the regulations governing the pharmaceutical industry is ensuring consumer safety. For example, part of the intention behind the DQSA regulations is to reduce potentially costly and life-threatening errors and oversights. The regulations are the latest development in a long-standing process through which the FDA and the equivalent organizations in the European Union have sought to protect public health. Errors in prescriptions or doses due to inaccurate labeling can cost billions of dollars and thousands of lives. Thus, product identification standards have been drawn up in order to ensure patient safety through obligatory validations, audit trails, electronic signatures, copies of records and record retention.

This places labeling standards at the heart of pharmaceutical companies' efforts to maintain safety standards, eliminate errors and guarantee accuracy. A modern labeling solution should be efficient, accurate, able to operate without paper versions of records and designed to work across an entire organization, managing the complete label lifecycle.

This approach, where data is controlled and managed throughout the label lifecycle, is especially relevant for pharmaceutical companies, as products move from the factory to distribution and through various packaging iterations. Keeping track of the progress of a product so that it remains safe and can be delivered to its intended destination is of critical importance. Labeling is an integral part of this process.



Beyond issues of human health, pharmaceutical companies have to beware of the threats from counterfeiters and from agents diverting pharmaceutical products. A cloud-based labeling solution that includes a central document management system helps with the fight against these twin issues, since it is easier to secure label files and provide multiple levels of role-based security to limit access to data.

Summary

To ensure label accuracy and protect patient safety, pharmaceutical companies are best placed if they adopt a cloud-based labeling approach that can manage the entire label lifecycle, offer complete transparency throughout the label production process and facilitate quality control procedures.

4. Reducing Costs


With tighter margins across the pharmaceutical sector, cost saving has become a central issue in the industry. Also, here a modern labeling solution can be of assistance by helping companies create faster, more efficient operations throughout their production process, from manufacturing to order fulfilment.

For example, if a large-scale manufacturer is able to label its goods more quickly, accurately and with better traceability, it will also be able to ship these goods and sell them more quickly.

In addition to the direct cost savings that can be achieved through efficiency measures, a cloud-based labeling solution helps to reduce and eliminate the losses caused by unplanned production delays and product re-working as a result of labeling errors.

In other cases, costs can be reduced simply through minimizing label variations and preventing duplication. By moving from printer code or printer-specific label formats to universal intelligent label templates one leading European generic pharmaceutical company was able to eliminate a high volume of duplication, creating significant cost savings through saving hundreds of hours spent on label change requests.

There is a common-sense calculation to cost savings in label production: if a company has a decentralized labeling operation, each facility that ships products to customers must update its label templates whenever a new element is introduced. This will include adding new fields to a label template, adding new barcodes and so on. In many cases, IT staff will be involved in these changes, at a high cost to the organization. Alternatively, label design and amendment may be sub-contracted to an outside agency, with further cost implications and potential time delays.



By contrast, a centralized, cloud-based labeling solution helps to reduce direct and indirect costs through minimizing the labor, time and expertise required to maintain label formats, make changes and create new labels. The repetition and redundant effort present in a decentralized labeling operation can be eliminated, freeing up IT staff for more productive work and saving hundreds or even thousands of man-hours, along with vast amounts of money.

Summary

Prevailing market conditions are placing pressure on pharmaceutical companies to reduce their operating costs. Introducing a cloud-based labeling solution increases operational efficiency, makes the best use of internal resources and reduces label errors, thereby saving time and money and mitigating the risks associated with quarantines and recalls.

5. Agility

Customers and the markets in which they live are becoming increasingly involved in how products are labeled and shipped and are, in many cases, placing demands on pharmaceutical companies that they cannot ignore. Added to this are the demands of meeting local and regional requirements for labeling that international pharmaceutical companies must face.

To adequately meet the demands of so many different stakeholders, pharmaceutical companies need to be agile and capable of meeting new requirements quickly. Modern labeling solutions enable this responsiveness and help companies manage the complexity of location-specific labeling requirements, while maintaining consistency and efficiency.

A modern labeling solution will include a centralized document management system and the capacity to scale standardized processes across an extended global supply chain. Such a system should also be able to connect with MES and ERP systems and facilitate data integration programs. Adopting this approach will make a labeling system more responsive to enterprise demands.

Many manufacturers today contract some of their production to third parties. Whether companies choose to integrate contractors into their ERP system or elect to extend their labeling platform to contractors, a cloud-based labeling solution will ensure that the labeling process remains consistent across all sites.



Summary

Where labels are being printed at a number of different locations, adopting a cloud-based labeling approach means that products can be launched faster, compliance with new regulations can be achieved more easily and return on investment can be increased. Pharmaceutical companies can become more agile, as they are able to accommodate change requests more easily and quickly across a wide range of sites and throughout the supply chain.

6. Supply Chain Management

Effective supply chain management is a central element of 21st century commercial life. Pharmaceutical companies have to collaborate with business partners in even more complex ways, across geographical and product boundaries. Deploying a cloud-based labeling solution can help them achieve consistency and efficiency in these partnerships.

Suppliers can be given access to a company's centralized labeling solution, meaning that whatever they supply comes correctly labeled and ready for distribution or integration into another production process. This saves time, eliminates a potential source of error and cost and ensures consistency across the supply chain.

Centralized labeling systems make the whole extended supply chain more responsive to change requests and deter diversion and counterfeiting through advanced labeling techniques.

By making use of web-enabled technology, a cloud-based labeling solution also improves internal collaboration by making it easier to extend access to business users across departments, offices and sites. Using a browser-based interface enables the labeling user to access and print centrally managed labels and data, thus improving label and brand consistency while reducing mislabeling. Having a web-based system is also the best way to manage a multi-user environment, and provides the transparency, tracking and access control highly regulated environments require.

Summary

By implementing a cloud-based labeling solution, pharmaceutical companies can enable collaboration and ensure consistency both internally and externally. Modern label management enables all relevant users to have access to the same, centralized labeling system and utilizes web-based technology to manage complex, multi-user environments.



7. Centralization

Since the dawn of globalization, every international company has had to deal with the global vs local dilemma: to what extent should a company centralize or localize key operations?

For pharmaceutical companies, centralization means being able to improve consistency, accuracy and accountability. However, the vast amount of local or regional regulations and requirements can make centralizing labeling a challenge. Pharmaceutical companies also seek to mitigate the risk of downtime in their production operations by spreading production centers, and their data and labeling functions, between different locations. It's therefore important to have flexibility to adopt a hybrid model that ensures the benefits of a centralized approach but offers multi-site capabilities to deliver a failover capability that provides local instance connectivity should the connection to headquarters be disrupted.

With a cloud-based labeling solution companies can standardize labeling globally while ensuring continuous operations, with complete control over how their labeling solution is deployed between headquarters and remote locations.


These capabilities are essential for companies that require continuous up-time and are concerned about labeling consistency and adhering to customer, regulatory and branding requirements across their global operations. A cloud-based approach to labeling delivers the flexibility that pharmaceutical companies require by ensuring they are able to select a deployment that best suits their business, products and processes, and adapts to the IT layout of the company in question.

Summary

A cloud-based labeling solution will be able to offer as much or as little centralization as any pharmaceutical company is ready to adopt. By selecting a solution that is flexible, companies can succeed in establishing 'one single source of truth' in their labeling systems, while still supporting local and regional variations in labeling.

Conclusion

As this report has outlined, implementing a centralized, standardized labeling solution offers pharmaceutical companies the opportunity to make profound improvements to their business processes, reaching far beyond label production.



When successfully implemented, a cloud-based labeling solution can yield dramatic results, including:

- Increased efficiency and streamlined compliance
- Greater label consistency and customer responsiveness
- Label template consolidation and a reduction in change requests
- Improved governance for label content and layouts
- A scalable platform for future growth

Agility, accuracy and compliance will be hallmarks of successful pharmaceutical companies going forward. To compete and thrive in an increasingly complex and challenging marketplace, pharmaceutical companies will have to rethink their processes and find ways of accomplishing more with less. This transformation starts with implementing a cloud-based labeling solution

Loftware Cloud: Transforming Labeling for Global Pharmaceutical Companies

Leading global pharmaceuticals companies are turning to Loftware's Enterprise Labeling Solution, Loftware Cloud, to help them overcome the challenges outlined in this document.

Loftware Cloud helps to provide the required levels of agility to ensure global pharmaceutical organizations are able to quickly respond to changes in customer, brand and regulatory requirements, while driving significant efficiencies across their supply chain. And, with flexibility at its core, you can move to globally standardize your labeling while still empowering individual sites or business units to make changes locally in the way that suits your business processes and organizational objectives.

Find out more about the powerful capabilities of Loftware Cloud and how it can help your organization by visiting www.loftware.com.



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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