A New Era for Factory Printing: How To Reduce Human Error, Accelerate Printing Times and Maintain Compliance

A White Paper from Kallik

KALLIK

Highly regulated industries require high levels of quality assurance throughout their labeling and artwork lifecycle to be successful; from the moment the labels are created, to the approval process, all the way through to factory printing. With regulations continuing to tighten, it is not enough to have a well managed process upstream only for this to ease up at the factory printing stage. This bad practice leaves the critical final segment of the labeling process with high margins for human error.

Technological innovation continues to be the answer to issues arising within the life sciences industry, but many stakeholders are reticent to changes, preferring to maintain traditional but outdated label management processes and heavily relying on weak standard operating procedures to ensure quality. The result of manual processes is often an increased likelihood of errors and subsequently recalls. It is reported that labeling and packaging errors account for between 35%-40% of all errors seen by the FDA. These are not only costly, but also damaging to a company's share prices, reputation and public confidence. Most importantly in the instance of life science companies, incorrect labeling has the potential to put patient's lives at risk. An intelligent labeling and artwork management solution can not only reduce human error, but also decrease printing times while maintaining regulatory compliance. Technology is not something for the life sciences industry to avoid, but rather embrace, particularly when it provides a competitive advantage.

Getting a new label to the production line can take months

Creating labels for new products or making changes to existing ones can take time. Prior to the printing stage, review and approval by multiple stakeholders is essential, including those from regulatory, marketing, production and supply chain. In most cases, if the label is changed to address feedback from the reviewers, then the approval process must be repeated. **It can take multiple iterations to get to the final approved label that all stakeholders agree on.**

Having an approved label is all well and good, but there are a variety of other factors to consider which could have an impact on the quality and accuracy of the printed label. Manufacturers simply cannot risk finding these issues during production, therefore any new or changed labels must be test printed on the real production printers with the correct label stock and with a sample of the variable data that matches real-life production.

Approving a new or updated label can therefore take anything from 2 to 6 months. A large contribution to this timeframe is the drawn-out process of review and approval. Furthermore, local translations are necessary for products sold on an international scale, even more so when regulations can differ between countries. The long, arduous task of ensuring that final label layouts and content are correct prior to production consumes a significant amount of valuable time and resources. This equates to time and money that many companies cannot afford to waste.

Traditional approaches are leaving manufacturers exposed

Although it may seem straightforward, most organizations tend to implement completely distinct systems and processes for each project. However, one single solution that is applicable to all projects would vastly reduce complexity, duplication of effort and label inconsistencies. Furthermore, these processes are frequently disconnected, relying on emails, printed documents and other uncontrolled forms of communication. This not only leads to oversight and errors, but also makes it incredibly difficult to demonstrate a clear audit trail underpinning proof of compliance.

Despite efforts to maintain high levels of quality control, errors still happen. This is primarily due to the fact that, in most organizations, factory printing is generally a manual rather than an automated process. The packaging and distribution of products is often complex and multi-layered. For example, two or more individual products packaged together may constitute a 'kit', which requires its own unique device identifier (UDI). These same products may also be sold individually, requiring a separate UDI for these instances. When factory print solutions are disconnected from the rest of the process, there is a heavy reliance on the knowledge of the print operators to ensure that the correct label is applied to both the packaging of the kit as well as its individual components. Manually identifying the correct label leaves great margins for human error, even amongst the most skilled and experienced operators.

Though in some cases there is a search option available to perform on a local computer to help, usually the operator will need to scroll through a long list of labels in order to source each label that they require. This process has to be repeated for the inner label, outer label, box label, carton label and patient label, making it incredibly easy to mix them up, as well as being a lengthy process. It is entirely down to the operator to make these decisions, and sometimes, regrettably, their decision is incorrect. It seems unreasonable to leave these labeling decisions down to the print operator, particularly when the actual size of the product is likely known to the organisation's ERP system. If these systems were connected, however, the ERP system could automatically identify the correct label size to print. This would leave the print operator with the simple task of applying the correctly printed label to the product, something that is far easier to get right the first time.

The consequences of getting it wrong are significant

Labeling errors happen all too frequently without digital, interconnected systems in place. For the end-user, seemingly minor errors can have major consequences. This can include the misuse of the product, incorrect dosage information on pharmaceutical products or incorrect instructions on medical devices, which can lead to patient injury or even be fatal. There seems to be little value in going through an extensive, highly controlled process upstream only to leave one of the most complex, crucial parts of the process so openly exposed to human error at the printing stage. Automating this process would be the logical approach, but many companies are slow to implement this. Instead of adopting a company-wide global labeling and artwork management solution, they opt for individual, local instances of labeling software installed solely for printing the labels in the factory.

Often there is a wide variety of different print systems used across the business, typically as a result of mergers and acquisition, meaning there is no common approach to printing or a single source of truth. The disconnection between the upstream label approval process and the downstream printing process leaves labeling projects prone to human error. Even when mistakes are rare, in highly regulated industries, every mistake counts; the impact of errors and recalls on both patients and the company itself can be devastating. There are countless instances with the potential to go wrong that could be completely avoided by an intelligent, end-to-end system. A print operator manually mistyping a batch number or an expiry date by just one incorrect character can have a huge impact. Similarly, patient specific products can require an input of up to 50 digits by the print operator to generate the correct label, and one error can lead to the wrong label or the wrong information being used.

This risk is unnecessary. Connected systems can simply calculate and populate these details automatically, removing the chances of errors. The ideal solution is an automated factory process, whereby the operator follows a set workflow and the only choice they need to make is what task to complete next.

Connect the disconnected

Regulated industries should not be hesitant when it comes to digitizing their printing process. An intelligent label and artwork management solution, designed specifically to overcome the challenges of highly regulated industries, can ensure that the right label and the right variable batch information is automatically provided to the print operator in the factory.

This type of solution can inform print operators what to do with the label and where to put it. It can recognise whether the label is part of a set, and if so, ensure that the correct quantities of labels are all printed at the same time. Even in cases where a selection of printed labels are applied to the product further along in the process, it is better to print all appropriate labels at the same time to be applied when the products are placed in the final carton. This way, there is no reliance on multiple operators to make labeling decisions; the process is reduced to one operator. A connected solution also means the print job will be sent to the correct printer, with the right capabilities for the size and scale of the label, subsequently avoiding misprints or barcodes not printing properly.

Hosting this intelligence within a centralized solution reduces the risk of errors. Another advantage of connected systems at the factory printing stage is the ability to test-print one label prior to printing the batch in order to verify that all label information is accurate. This can also be repeated at the end of the printing job with a verification label to ensure the printing process for each label has run smoothly, allowing the print operator to maintain a high level of quality and accuracy. Everything that could go wrong in manual processes is seamlessly removed, and incorporated into an end-to-end process that is fully compliant with industry regulations.

There are huge benefits to implementing an integrated labeling and artwork management system

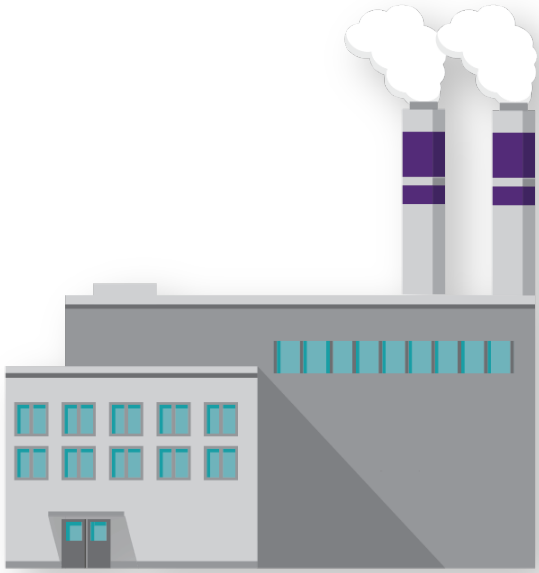
When setting up a label printing system, the software captures where the printers are located, the type of printers they are and the ports they are using, giving the system a global view of all available printing resources. As the company is managing all labeling content centrally, it is possible to know the label size and print quality requirements, enabling the correct printer and printer settings to be selected for each and every label. When labels in a subsequent print job are a different size, a message is automatically sent to the print operator to change the label stock. This approach almost eliminates the risk of operator errors, reducing waste and ensuring the correct quality and quantity of labels are printed correctly the first time.

Factory printing needs to be carefully managed. It is the final stage of a very complex, tightly controlled process. Manual processes only allow for uncontrolled choices and flexibility, which increase the chances of errors at the final hurdle. A global labeling solution enables full control and management of all labeling content in one centralized platform. This provides all stakeholders with full end-to-end visibility of the entire labeling process, from conception to print. Any discrepancies at any point in the process can subsequently surface much earlier in the process, further reducing the risk of downstream stockouts.

Furthermore, implementing an end-to-end solution means that a comprehensive audit log with reporting tools can be obtained from anywhere in the world. Print runs and variable information can easily be tracked and reviewed in this way in the event of compliance concerns. As well as proving compliance, audit reports can also help to identify process failures, pinpointing when, where, and how a problem arose, which helps to prevent the repetition of costly errors. Every single printer and print job across the entire enterprise is known to the system, and all events can be captured in a single audit log irrespective of the product type, brand, factory, location, print operator, or whichever variant of label is chosen for printing. This approach enables the generation of an audit trail in a matter of seconds that can span multiple locations to prove compliance, instead of investigating failures for days, weeks or even months.

The benefits of a connected system do not stop here. An audit log can also help to reconcile scrap labels. For quality control and compliance reporting purposes, the label record should match the quantity of manufactured products and maintain a record of the quantity of labels scrapped. Through connecting the manufacturing and printing processes, the exact number and type of required labels for each batch can be printed, avoiding the time and effort involved in reconciling differences between the two. If a label needs to be reprinted, a connected approach makes this much simpler; being able to reprint individual labels from data recorded in the audit log eliminates the need to re-print the whole batch. It also eliminates the need to re-import data or override manufacturing systems, which can otherwise result in disruption and delay to manufacturing processes. Where labels are serialized, connected systems make it possible to reprint the individual label while ensuring that the correct sequences are maintained, protecting the integrity of track and trace systems. These benefits also extend to less granular variable data, such as product expiry dates. In these reprinting instances, system intelligence automatically reverts the product expiry date based on the original manufacturing date rather than the date that the label was reprinted, which significantly reduces the risk of errors.

In Kallik's latest version of our own labeling and artwork management solution, Veraciti™, our customers in the medical device, pharmaceutical, cosmetics, and oil and lubricants industries are benefiting from decreases in project completion times and ensured compliance, signifying the importance of embracing new technology in highly regulated industries..



About Kallik

Kallik, the enterprise labeling company, provides regulated industries with a responsive, end-to-end label management platform they can trust.

Its cloud-based labeling platform, Veraciti™, delivers definitive compliance and supply chain efficiency for all the content assets that make up product packaging, labeling and customer information documents. From barcodes to safety symbols and text, Veraciti manages any format, in any territory, on any material and via any channel - with complete reliability and traceability.

Medical device manufacturers, pharmaceutical firms, chemical and cosmetics companies use Kallik to deliver trust in their labeling, confidence in their brand and integrity in their process.

To find out how we can support label and artwork management transformation in your business, please get in touch by emailing us at enquiries@kallik.com.