# Reducing Errors in Factory Print: The Case for Labeling Digitalization

A White Paper from Kallik

KALLIK

In rigorously-regulated and safety-sensitive industries such as medical device manufacturer and pharmaceutical supply, it is too risky to leave the accuracy of market-facing product information to chance. The following e-book sets out the case for more coordinated control of all forms of product labeling, from artwork design to final printing on the shop floor.

# The far reaches of 'factory print'

'Factory labeling' or 'factory print' applies to all forms of printed label and customer information that goes out with a physical product, and its business-criticality cannot be underestimated.

In the context of medical device manufacturer and pharmaceutical/biotech companies, and indeed other highly regulated and potentially hazardous markets, labeling accuracy or inaccuracy can have a potentially significant bearing on human safety. Failure to include the latest correct instructions, warnings or safety symbols could have a direct bearing on people's health and wellbeing. Certainly it could result in costly product recalls and/or withdrawal from the market.

Under US FDA requirements, 'labeling' encompasses Instructions-for-Use (IFU) booklets and promotional materials, for instance, as well as the physical label on the product, packet or carton. With regards to labeling for drug delivery devices, the device itself needs to have a label attached to it. The device packaging, whether it be some sort of pouch, polythene bag or cardboard carton, will also need labeling. So will the shipper.

These materials together comprise a considerable source of commercial risk, if not controlled carefully. FDA reports indicate that somewhere between 50% and 75% of errors highlighted in safety warnings and product recall notices involve some form of labeling mistake. Typically these errors are also recorded very publicly on the Wikipedia pages of the company involved, potentially affecting not just their share price but also public confidence.

While the information displayed on different labeling formats – eg product packet/drug delivery device vs shipping carton - will be similar, the quantities are usually different so it's imperative that the relationship between the product, its associated labeling and types of packaging are correctly maintained, to avoid incorrect quantities in the box being shipped to hospitals, for example. Otherwise this could result in serious consequences for the patient downstream, if procedures are disrupted due to unforeseen last-minute stock shortages.

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# Why optimized control should start with label artwork

Changes to the layout of a label, or new label artworks for new products, need to be circulated around multiple stakeholders for review and approval before they can progress to the print stage. These stakeholders include regulatory, marketing, brand management, production and supply-chain teams.

Once the artwork has been approved, the labels will then be test-printed as part of the approval process. Where quality control is paramount, these labels will be test-printed on the actual printer with the correct label stock, using a sample of the variable data that reflects real-life production.

The approval process for a new batch of labels can take anywhere between two and six months. This is because people are personally accountable for reviewing changes and making decisions – even more so these days with electronic signatures. Often requirements are different in each country, necessitating local translations. The overall process from identifying new requirements through to running localized test prints in the factory consumes a huge amount of valuable time and resources to ensure the final label layouts and content are correct before anything goes into production.

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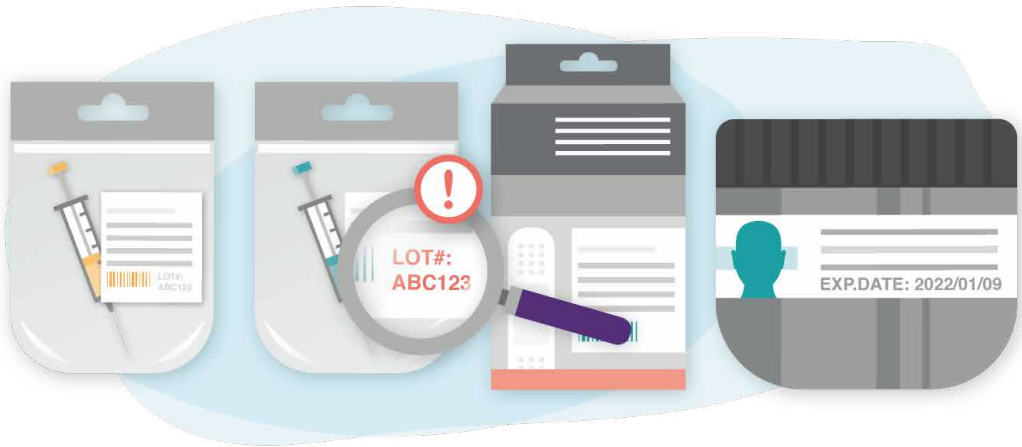
# Sources of potential risk

Problems with label accuracy can arise due to the disconnect that commonly exists between the aforementioned process and the print operator in the factory - who is responsible for making sure the right labels are printed for each product and use case.

The first challenge for operators is correctly identifying the products in front of them. Even if these individuals are skilled and experienced, and recognize the different types of products for which labels are required, they must then identify the correct label type.

Although there may be some form of rudimentary 'look-up' function they can perform on a local PC, more often than not the operator will need to scroll through a long list of labels to try to recognize the exact label needed at that particular time - whether this be the inner label, outer label, box label, carton label or patient label. The scope for human error is not insignificant in this manual labeling management scenario.



# Counting the cost of wrong decisions

As already noted, the risk arising in the event of a labeling error can be considerable. An error, omission or lack of clarity/completeness in the information provided could result in a product being misused, with potentially serious consequences. If a patient-specific medicinal product carries the wrong dosage information, the risk could be patient intoxication/injury or even death.

Having gone to all the trouble of getting everything right upstream (an extensive, professional review and approval process), organizations should not then rely on a relatively low-skilled individual in a remote factory to make a series of complex decisions in an attempt to place the right labels on the right products.

Factory-level print scenarios can be even more involved, too – for instance, in relation to the number of variants in size required for a single product, each requiring its own accurate dosage information. With disconnected factory print solutions, it's left to the operator to select the label specifying the correct size and associated advice information, introducing further scope for errors and safety risk.

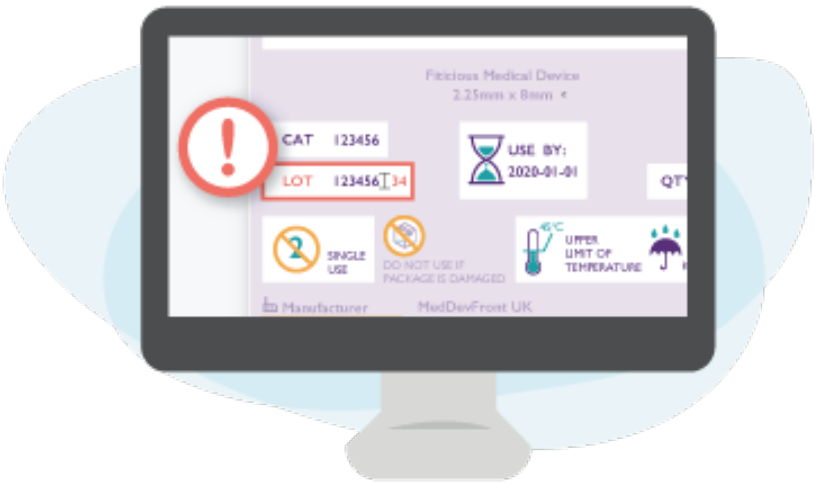
It makes no sense to leave this kind of decision to the print operator, when the actual size/measure of the product is known to the organization's enterprise resource planning (ERP) system. If connected to the factory-print solution, the ERP system could automatically tell the printer to print the right label with the correct variable information on it. All the operator needs to do then is to apply the right label to the right product.

> 'Factory printing takes place within a carefully-controlled environment – specifically at the end part of a very long, highly-regulated process. There's little sense in allowing uncontrolled choice and flexibility in the latter stages if everything else has been tightly managed up to that point – and vice versa.'

# Why the disconnect?

Typically, organizations take one of two approaches to managing their labeling at the factory-print level. They either adopt a company-wide global labeling and artwork management solution, or implement local instances of software solely for printing labels in their factory.

It is relatively easy to install a factory label printing system with no connection to anything else and feed a piece of paper to it - and to lean on someone with experience who seems to know what they're doing. And 99% of the time this works fine as a low-cost/low-tech solution - but it's the impact of the 1% of the time, when something does go wrong, that can be devastating. The 1% chance of a labeling error on an innocuous high-street consumer product is unlikely to be the end of the world, but in the context of pharmaceutical or medical device products if the error results in an adverse event for a patient, then the consequences will be severe.



Again, variable data can magnify the risk. An operator could too easily enter a typo when keying in a batch or LOT number, or input the wrong one, or the wrong expiry date. So it is remarkable that organizations risk manual processes, when there is a more failsafe alternative. Calculating expiry dates via connected systems is simple, and removes any margin for error. The same applies with patient-specific variable data. Patient-specific products can require up to 50 digits to be typed in by the print operator to generate the correct label. If any one of these is wrong, the wrong information goes on the label and the label can be misleading. So why do firms risk it, when systems could be taking care of this automatically?

# Overcoming inertia by identifying resource wastage

Linking up- and downstream labeling activities is not nearly as onerous as companies perceive it to be, nor more 'hassle' than having people double- and triple-checking printed labels both before the label reaches the production line , and once the label has been printed and applied in the factory. Indeed, the amount of time and resources that go into checking and rechecking labeling at the various stages of design and print often remains invisible to executive management. It's only when this is brought to light that companies realize just how much of a waste of valuable resources this has been – resources that could be better utilized in increasing production and reducing downtime.

# Driving transformation

Label management and automation on the factory floor is the optimal way forward if organizations want to free themselves from the risk and resource-intensiveness of operator-led label printing. In an automated, joined-up scenario, the only decision that falls to the operator is which job to process next.

Beyond that, the operator is automatically given the right label and the variable batch information, and instructed what to do with that label and where to put it. If the label is part of a set, the correct quantities of labels are all printed at the same time. Even where a selection of the printed labels is applied further downstream, it is still better to print all the labels at the same time - ready to be applied when the products are placed in the final carton. Instead of asking three separate operators to make a decision, everything is now done by one operator.

This solution also prevents scenarios in which operators send a print job to the wrong printer, or the wrong type of printer, resulting in misprints or the barcode not printing properly. Or where the operator inadvertently changes the print speed or the temperature settings in the printer, leading to dosage symbols being misread or not recognized properly, or part of the label being missed off due to wrong label stock being used for a particular type of label.

With a connected solution, the system automatically knows which type of labels required to run 'Job A' vs 'Job B', and can advise the operator to change the label stock accordingly.

# The wider benefits of centralized control

Holding all of the intelligence about the different types of printers and their capabilities within a centralized labeling management solution makes it easier to route the right jobs to the right printers, reducing the risk of errors.

In this context, a factory print system will capture where the printers are physically, which ports they're connected to, and the types of printers they are, so the system has a global view of all available printing resources.

At the same time, because all labeling content is being coordinated centrally, the label size and the print-quality requirements are held here too, ensuring that the correct printer and printer settings are selected for every label.

# Final checks & balances

Factory printing takes place within a carefully-controlled environment – specifically at the end part of a very long, highly-regulated process. There's little sense in allowing uncontrolled choice and flexibility in the latter stages if everything else has been tightly managed up to that point – and vice versa.

Rather, the management of all labeling content should ideally take place via one central platform that provides all stakeholders with full end-to-end visibility of the label design and print process. Any discrepancies between label design and print capabilities can then be surfaced much earlier in the process, further reducing the risk of anything going awry – with potentially serious safety or commercial consequences.