BOB TILLING, KALLIK

Bob Tilling, Business Development Manager at Kallik, has spent most of the last 20 years working with companies to help them identify and implement solutions to overcome challenges in the factory-based labelling of pharmaceuticals and medical devices. His experience is gained from having first-hand experience with over 80 company-wide factory labelling implementations with customers located across the EU and US. The focus of his effort has been reducing factory labelling errors at print time to reduce risks of non-compliance, achieved by reducing operator input and automating the print processes wherever possible.

In this interview, Mr Tilling shares his insights on best practice for factory labelling.

Q Firstly, can we define what we mean by "factory labelling", and the labels this applies to?

A "Factory labelling" or "factory print" applies to all forms of printed label. Considering labelling 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 labelling as will the shipper. Whilst these labels would be similar, the quantities are usually different so it's imperative that the relationship between the devices, their associate labelling and types of packaging are correctly maintained to avoid incorrect quantities in the box being shipped to, for example, the hospital. This could otherwise result in serious consequences for the patient downstream due to operations being disrupted resulting from unforeseen stock-outs.

Q What key criteria need to be addressed as part of a factory labelling solution?

A Firstly, factory labelling represents a much bigger task than most realise. If you look at the US FDA requirements, we know that labelling encompasses IFUs, booklets, promotional materials as well as the label. We also know that from their reports that somewhere between 50 and 75% of errors that the FDA highlight are based on some sort of labelling error. These errors also get reported on the Wikipedia pages of medical device and pharma companies so these issues can become highly transparent and potentially not only affect an organisation's share price but also public confidence.

Q Before getting into the specifics of factory labelling, can you share some insight of what's involved in either creating a new label or modifying an existing one?

A Changes or new label artworks for new products need to be circulated around multiple stakeholders for review and approval before reaching the print stage. This group includes regulatory, marketing, brand management, production and supply chain teams. Once that label's 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 with a sample of the variable data that matches real-life production. The approval process for a new bath of labels can take anything from 2-6 months.

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Q What are the main reasons behind this being a lengthy process?

A It comes down to time taken to review changes and make decisions in the context of being personally accountable – even more so these days with electronic signatures. Often requirements are different in each country involving the need for local translations. The overall process from identifying new requirements through to running localised 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 going into production.

Q This all sounds fairly straightforward, so what tends to go wrong?

A Problems can arise with the disconnect that exists between the aforementioned process and the print operator in the factory responsible for making sure the right labels get printed for the right products. The first challenge for operators is to identify what products they have in front of them. Even if they are skilled, experienced and recognise the different types of products they need to

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print labels for, they then need to identify the correct label type. Sometimes there is some form of look-up they can perform on a local PC to help, but often the operator will need to scroll through a long list of labels to try to recognise the label needed at that particular time, whether this be the inner label, outer label, box label, carton label or patient label. The operator has to make this decision and sometimes this decision is wrong.

Q What's the impact of making the wrong decision at this point in the process?

A A product could be mislabelled, a product could carry the wrong information, a label could be missing out of the required set or possibly a combination of these things might occur. This could result in the product being misused, patient specific pharmaceutical products could even carry the wrong dosage, potentially leading to patient injury or even death.

Having gone to all the trouble of getting everything right upstream, organisations should not then rely on one individual in a factory to make a whole host of selections to attempt to get the right label on the right product. In most people's minds, there would be little point in going through an extensive upstream review and approval process and then leave it to a relatively low skilled individual in a remote factory to make a series of complex decisions to attempt to place the right labels on the right products.

Also, it's not just product types that can change, it's also the number of variants in size for a single product - for example selecting the correct label for a specific size and dose of transdermal patch. With disconnected factory print solutions, it's left to the operator to select the label specifying the correct size, introducing opportunities for mistakes. It makes no sense to leave this decision to the print operator when the actual size of the product is known to the organisation's enterprise resource planning (ERP) system. If connected to the factory print solution, the ERP system could automatically tell the printer to print the label with the correct size on it. All the operator then needs to do is to apply the correctly printed label to the correct product.

Q This seems a logical approach, so why doesn't this happen today?

A Organisations either take one of two approaches. Either they adopt a company-wide global labelling and artwork management solution or they tend to have local instances of software installed solely for printing the label in the factory. It's easy to install a factory label printing system with no connection to anything else and feed a piece of paper to it. It's also easy to lean on somebody who's got some experience and seems to know what they're doing. 99% of the time it works fine as a low cost - low tech solution, but it's the impact of the 1% when it goes wrong that causes the problem. The 1% chance of a labelling error on a high-street product isn't going to be the end of the world, but in the context of pharmaceutical products, if the error leads to adverse effect on a patient, then the consequences are severe.

Again this can apply to variable data. Why ask an operator to type in a batch number or LOT number? What if they type it incorrectly? What if they choose the wrong one? Similarly, why let an operator type in an expiry date? Calculating expiry dates with connected systems is simple and takes away any margin for error. Similarly this can apply to 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.

Q Why aren't these localised print solutions connected to upstream production systems as you suggest? Surely it can't be that difficult to do?

A It isn't that difficult to do, but it's perceived to be more troublesome to do than have people double and triple checking printed labels both before the label reaches the factory and after the label has been printed and applied in the factory. It's often the case that the amount of time an organisation spends checking and rechecking the label at the various stages of design and print remains invisible to executive management. It's not until this is brought to light that there is a realisation that there is a waste of valuable resources that could otherwise be better utilised increasing production and reducing downtime.

Q In your view, what would be the ideal solution to overcome the problems you've talked about?

A The ideal solution is automation on the factory floor where the only choice the operator makes is which job will I do next? From then on, they are automatically given the right label, they're automatically given the variable batch information and they're told 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 are 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. In this way, you're not asking three separate operators to make a decision, it's all done by one operator.

The other thing that often goes wrong is that the operator will send the print job to the wrong printer or the wrong type of printer, resulting in misprints or the barcode not printing properly because the printer may not be capable of printing it to the required size or scale. The operator may change the print speed or the temperature settings in the printer, leading to issues such as dosage symbols being misread or not recognised properly, or part of the label can be missing due to wrong paper stock being used to print a certain type of label.

With a connected solution, the system knows what stock you used to run "Job A", if you move to "Job B", the system knows you need to change the label stock. The system can then tell the operator to change the stock rather than relying on him or her to select the correct stock?

Q It sounds like you're suggesting that holding the intelligence relating to the different types of printers and printer

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capabilities within centralised solution makes it easier to route the right jobs to the right printers, reducing the risk of errors.

A Exactly that. Such a factory print system will capture where the printers are physically, what ports they're on and what types of printers they are so the system has a global view of all available printing resources. At the same time, because you're managing all labelling content centrally, you know the label size and the print quality requirements to enable the correct printer and printer settings to be selected for each and every label. You'll also know that when the labels to be printed in a subsequent print job are of a different size, a message automatically gets sent to the operator to change the label stock. This approach takes away the risk of operator errors, reduces wastage and ensures the right quality and quantity of labels are printed and are right first time.

Q Are there any other insights you'd like to share about deploying a factory print solution?

A Factory print takes place within a carefully controlled environment. It's also the end part of a very long, highly regulated process. There's little sense in allowing uncontrolled choice and flexibility at the end if you tightly control everything up to that point. So unless you tighten the process up at the final print stage, there's really little point in running a set of tightly controlled processes further upstream.

At its core, a better approach allows the management of all labelling content in 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 downstream stock-outs.

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