

Error-Free Labeling—Accuracy, Traceability, and Compliance

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In an era of intense media pressure, growing patient power, and escalating litigation, it is extraordinary that so many medical device recalls are due to labeling errors. After years of robust, highly compliant medical research and product design, ensuring the correct information is included with each device should be a given.

Yet, errors persist; in a recent vision systems survey hosted by PRISYM ID, over 45% of respondents' organizations either sometimes or frequently had quality control issues with their labels during the production process. The reason? Two-thirds (67%) cited human error, which, given the processes currently used to check the printed labels, should be no surprise.

There is no consistency in the label print/check process across the medical device industry. Some organizations adopt a first and/or last print run check, or just opt for a random check, assuming consistency across the rest of the run. Others adopt the template approach, using a label mask to ensure information or images have been printed in each of several fields. However, with no need to verify that the information is accurate or image correct, this model can still result in serious labeling errors.

In addition, printers are famously inconsistent. From ribbon creasing to data conflict, the print run can be compromised and information confused. What is the

potential impact on a clinician looking to embed a device within a patient when the measurement advice has been misprinted as 12 rather than 1.2 due to print underburn, which has led to fading? How can an organization confidently allocate a device when the barcode is unreadable due to overburn?

The combination of human and printer fallibility can only lead to mistakes, and, as a result, the industry continues to accept print errors, and the attendant implications of potential product recalls, expensive legal action, and brand damage.

Auditable Process

Medical device manufacturers do not only need to ensure label accuracy; organizations also need complete traceability. To respond to FDA requirements, medical device manufacturers need to be able to demonstrate the full audit trail—from who designed the label, including how the data is checked, validated, and approved, to the design approval process, what was sent to the printer, and, critically, what was actually printed and failures managed/reprinted.

Sadly, in far too many cases, the last components of this process are either managed manually or overlooked completely; too much trust is placed on what was sent to the printer instead of what was actually printed.

Organizations require not only an audit log of the print output but also a log of what was checked, how it was checked and, critically, what action was taken in the event of label failure.

Automating Process

So why today do just 20% of organizations use vision systems to inspect print labels? The use of a digital vision inspection unit that takes an image of the printed label combined with software that compares that image against a control or sample removes the need for manual checking and can be conducted rapidly, with no impact on the production process.

However, the limitation of traditional vision system software has been that they are separate from the label design package/process. This created not only the need to train the vision system to recognize the checking criteria, but also resulted in a separate audit log of label checks.

The only way to truly streamline and automate this process, avoiding the risk of human error while also delivering a robust, secure source of information to support both internal and external audits, is to create a single end-to-end solution from design creation through visual check and audit creation in a single software solution.

Taking this approach, the vision system detects errors, such as incorrect barcodes and label elements that are unreadable to the human eye. Additionally, it flags lines or creases due to ribbon creases, and poorly defined characters or print that has been offset. Further, the vision system also creates a single source of design-to-print label information that can be used both internally and externally—internally to highlight specific printer/operator problems that can be rapidly addressed, and

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externally to provide an end-to-end audit trail that minimizes the risk of legal action or compliance breach.

Conclusion

Ensuring label integrity has traditionally been a two-stage process, with the print process woefully under managed; it is handled, at best, on an ad-hoc basis. This print and hope attitude is not sustainable, nor does it reflect the state-of-the-art processes employed at every other stage of manufacturing and delivery that have minimized human intervention and eradicated any risk of manual error.

By adopting a vision system that is integrated with the original label design package, medical device manufacturers can finally eliminate the potential for human error within label design and print, reinforcing compliance and dramatically reducing the risk of labeling errors and product recalls.

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