Automation: The Definition of Common Sense

Manual labelling processes are inefficient at tackling the many factors that result in product recalls. Therefore, automated solutions must be considered to reduce risk, save time, and lower costs

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Companies' continued reliance on manual processes and disparate labelling systems often culminates in pricey product recalls. In 2018, the return of over a million units and 9% of all medical device recall events were due to labelling issues. Organisations are known to spend as much as US $350,000 for every global label change. However, despite opportunities to de-risk the process through automated technologies, many persist with archaic methodologies that leave them vulnerable to human error. This absurdity is as unsustainable as it is avoidable.

As global regulations stiffen and the cost of noncompliance climbs, manufacturers must find a method to end the madness. Those who do will not only remove risk from their business, they will unlock the potential for additional cost savings that could transform the bottom line.

Labelling errors are a recurring reality for medical devices. The scale of the problem has barely shifted since 2012 when, just like now, around 10% of product recalls were label related. However, as label content becomes more complex with the introduction of new regulations, this figure will only increase if companies do not proactively review and strengthen their labelling infrastructure. The telltale signs of suboptimal operations are evident in the most prevalent causes of labelling recalls.

Wrong Label on the Wrong Product

It only takes one stray label or instruction for use (IFU) to cause a product recall.

However, an over-reliance on manual processes and weak standard operating procedures leave many companies exposed to the risk. It is not unusual for labels to be printed in batches and spread across the shop floor during a work order process, but this increases the risk of reconciling the wrong label or IFU with the wrong product. When this occurs, recall is the only viable option.

The right labelling system with the right tools can help eliminate this problem. One option is to deploy 'just in time' labelling and IFU printing at the point of packaging. Alternatively, using an integrated solution that pulls label-specific information from other business systems to enable master data management can give organisations greater control. These rule-based, automated systems can be configured to utilise barcode scanning of the box, label, and IFU to ensure reconciliation is correct.

Labels with Printing Errors

Sometimes, despite label content being accurate and approved, unexpected hardware or software failure can trigger dangerous printing errors. A trivial issue like a faulty print ribbon can lead to missing, unreadable, or misinterpreted content. When this goes undetected and products reach the supply chain, regulations are breached and patient safety is put at risk. Organisations need to ensure they have robust mechanisms in place to assure batch integrity. However, while many companies still rely on manual and random inspection, a better approach is to deploy a degree of automation. Standalone vision inspection systems or semi-automated inspection processes are both good options. The most effective approach is to integrate the label design and print process with vision hardware, allowing you to inspect every field on every label

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at the time of printing. Vision systems enable 100% automated inspection of all labels and can capture defects that are not easily identifiable by the human eye. This approach reduces time and risk.

Incorrect Market-Specific Content

Managing market-specific content is one of the biggest labelling challenges. Processes must be responsive to the nuances of local and international regulation and robust enough to label products for multiple countries with a single label. Due to the complexities of language translation, unique device identifier requirements, and symbology, companies would be ill-advised to maintain manual processes. Deploying humans to check every character and phrase on every label is time-consuming, costly, and risky. A safer alternative is to deploy an integrated labelling system that allows for accountability and control of master datasets. The best systems will have a ‘regulatory rule engine’ and version comparison tools to ensure all labels are checked for compliance with local regulations.

Master Data Errors

Linking labels to a master data source removes many of the weak links in traditional processes. A ‘single source of the truth’ for product data reduces the risk of human error and provides a platform for the transformative benefits of automation. However, costly master data errors can still occur if the system does not have the right tools and checks in place. For example, most integrated systems will link directly to an event-related potential (ERP). However, data modifications in that ERP could impose changes on the label that will go undetected if your labelling system does not have version control or mechanisms to approve workflows. An effective system will have a ‘notification centre’ that alerts users to tasks relating to supplementary data, as well as a fully configurable rules engine and review/approval process that flags outstanding errors.

Transformation Through Automation

The implications of product recall are significant; the direct and indirect costs of removing a product from the market, addressing the cause, and managing brand reputation can be hugely expensive, and the potential human costs are unquantifiable. However, the risk can be mitigated with better use of digital innovation. Technology is not a panacea, but, with a more considered application of it, companies can automate labelling processes in ways that remove risk, reduce cost, and strengthen validation. Integrated solutions can help organisations establish labelling systems that are robust, repeatable, and traceable.

Achieving this requires a holistic view of your labelling operations and the touchpoints these have with the rest of your organisation, rather than trying to resolve issues in isolation. The most progressive organisations have made a proactive assessment of market risk and invested in validated labelling platforms that offer complete label integrity to meet strict regulations. The benefits have been substantial. One company’s deployment of an enterprise-based labelling system saved US $19 million a year by removing labelling errors. Another has shifted to ‘just in time’ labels and IFUs, yielding annual cost savings of US $8 million.

The technology landscape is varied and flexible. With vendors now offering cloud, Software-as-a-Service, on-premise, and hosted solutions, today’s systems are scalable to companies of all sizes and can be configured across a range of platforms. However, with a common fear of implementation, the best vendors will take a ‘lifetime partnership’ approach to help companies develop labelling strategies that respond to change and futureproof operations.

In a global marketplace underpinned by tight regulation, automated solutions present a timely opportunity for medical device companies to end the recurring insanity of labelling recalls. Integrated systems can facilitate greater control of labelling operations and help companies de-risk processes, drive efficiency, and increase profitability.

About the author

Craig Jones has the responsibility of understanding customer needs and industry challenges to drive solutions to improve efficiency, minimise risk, address regulatory requirements, and provide new approaches to business systems and processes. Craig has 15 years’ experience delivering validated label lifecycle management solutions to life science and healthcare industries, including medical device, pharma, and clinical trial organisations. His experience includes roles as an industry consultant, in IT management, and as a senior manager for global technical support and professional services.