Bringing Medical Product Labeling up to Standard

Warren Ward-Stacey

 Every medical device manufacturer accepts that in the current regulatory environment, with the Food and Drug Administration (FDA) demanding complete life cycle traceability of every product, accurate labeling is a necessity. Yet the reality is far from satisfactory: many companies have issues with label quality, not knowing what was printed, discarding pre-printed stock and needing to dispose of labeled products; whilst product recalls and field instances are endemic not due to the failure of research and development or manufacturing processes but inaccurate labeling information.

With the top tier of organizations now exploiting integrated electronic print and verification solutions to eliminate labeling errors, the FDA is set to turn its attention to the rest of the market. Warren Ward-Stacey, SVP Global Sales, Prisym ID, insists it is time for medical device companies of every size to accept the next regulatory era and put in place robust, highly integrated processes for printing and verifying label creation that minimize the risk of compliance failure whilst also providing the required complete lifecycle audit.

Evolving Landscape

The compliance landscape for any organization involved in the life sciences industry has changed radically over the past decade. From pharmaceutical companies to medical equipment manufacturers, organizations now face stringent demands for complete product lifecycle traceability and auditability.

The reasons are clear: failure to accurately label these critical devices can be life threatening – from the inaccurately labeled stent to the Class One Orthodontics Buccall SS tubes that were mislabeled as nickel-free, risking allergic reaction in patients or the pediatric tracheal tubes manufactured with an internal diameter smaller than indicated on the label.

In addition to damaged reputation associated with information inaccuracy, poor processes can result in huge fines from local regulators such as the Food and Drug Administration (FDA) or the Medicines and Healthcare Products Regulatory Agency

(MHRA), product recall and even complete operational shut down.

Undermining Quality

With labels undergoing multiple revisions during the product lifecycle in response to regulatory demands, medical companies recognize the need to implement incredibly robust processes for design and print of labels. Yet with information typically being pulled from multiple systems, often globally, ensuring the imagery matches the words and that both comply with local regulations is both highly intensive and time consuming.

Processes are typically highly manual, somewhat convoluted and require multiple authorizations and multiple scans – of both labels and products; and with information pulled from multiple disparate systems there is a risk of overlap, duplication and an information discrepancy – i.e. two versions of the truth.

As a result, despite the manually intensive effort, most companies accept a certain level of problems, incurring tickets for non-compliance from the FDA on an annual basis. Many companies also endure repeated failure of label printing, discarding swathes of labels that have been produced with the wrong text, imagery or unreadable quality.

This approach is not sustainable in today's regulatory environment. How can a business continue to invest heavily in innovative product design, high standards of manufacturing yet still risk warning letters and penalties from the FDA due to poor processes for product labeling? How can an organization that exploits real time online communication to streamline production and transform the supply chain, still rely on paper based authorization for this critical aspect of the operation?

Integrated and Verified

Traditional processes for label production i.e. understand what was sent vs. what was printed are no longer fit for purpose. And many companies recognize this fact, with growing numbers exploring Vision systems to undertake post print verification to ensure no errors have crept into the process – as a result of print problems, for example. But for many organizations the issue comes before verification – just how many can confidently confirm that the information sent to the printer is 100% accurate every single time?

To achieve a FDA validateable solution for final destination labels, medical device manufacturers need to embrace a fully integrated electronic print and validation solution that includes auditable security protocols and lifecycle documentation. By integrating information from the multiple source systems into a dedicated solution to ensure one version of the truth, a manufacturer removes the element of chance from the process and ensures information from production is delivered to the label at the time of print.

Combining this single source of the truth and with an in-built approval process – review, approve, print, reconcile - only approved imagery and data can be placed on the label. With this in place, the integrated print verification Vision solution undertakes an automated audit on the print process, ensuring the print process has

occurred correctly.

Taking this approach removes the chance for label errors, reducing tickets, minimizing wastage and avoiding duplication; whilst also delivering the complete lifecycle traceability demanded by the FDA and enabling rapid action to be taken should a product recall be required.

Regulatory Spotlight

Of course, despite widespread awareness of the problem, many companies are hoping to stay under the FDA radar, assuming the current emphasis on enforcing regulation for the top tier of organizations will continue. But with improvements in the available technology and the increasingly accessible nature of these solutions, the onus is now on organizations of all sizes to ensure that they adopt robust, highly integrated labeling processes that can reduce ticketing incidents as much as possible.

Furthermore, while hard to measure, there is no doubt that health service procurement is also taking into account the quality of labeling. With every health service globally looking to reduce incidents of malpractice and the escalating legal bills, those companies that contribute to a problem with a patient due to poor labeling are likely to be rapidly removed from the list of approved suppliers. Add in feedback from surgeons regarding the usability of devices – which by default will include the ease with which the device can be identified by its labeling - and good, accurate labeling also plays a key commercial role.

This is a critical component of the business. Industry legislation for medical device labeling and packaging is constantly evolving. And while many companies still argue the traditional approach is working; it isn't. For organizations making huge investments in research and development, streamlined production and excellent customer service, is it really worth jeopardizing business success by waiting for a major FDA investigation or public lambasting before bringing product labeling up to standard?

Warren Ward-Stacey is the Sales Director of PRISYM ID, responsible for leading and driving results from the global sales team. He has a detailed knowledge of the auto-ID industry with particular emphasis on label production techniques. Warren is passionate in identifying and securing new business opportunities, whilst building business within our existing global client base to create year on year revenue growth. His belief in delivering market leading products to gain customer satisfaction is infectious and result's in PRISYM ID having an enviable blue-chip customer base which is rapidly growing.