It’s Not About the Label: Taking a 360° View

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With a high percentage of voluntary recalls of medical devices caused by labeling and packaging defects, it’s easy to see why companies focus so much individual attention on the label as part of the production process. The implications of product recall are significant; efficiency, productivity and ROI take a major hit, whilst the potential damage to brand reputation and patient safety are equally severe. With the addition of regulatory fines for non-compliance, companies’ widespread focus on the label is perhaps understandable. But it’s also disproportionate and misplaced. In the battle to deliver safe, accurate and compliant product information to patients and end-users, it’s not about the label—it’s all about the data.

The costly mislabeling of medical devices is totally avoidable. Technologies that can give companies a 360° view of all their data assets and optimize them to create a fully integrated approach across the lifecycle can transform the production process. It’s time to shift the focus.

Fragmented Approach

Across the global medical device sector, the way in which many companies approach the design, creation and printing of labels is both variable and fragmented. Commonly, organizations regard labels as individual documents that present fixed pieces of content—and when changes are required they are forced to go back to the master file, modify individual content-rich documents and then reprint them. It’s an onerous—and often primitive—process that’s not only inefficient and costly, but also resource-intensive, a hostage to product updates and country-specific regulatory requirements, and prone to human error. And worse still, label data rarely integrates with other organizational business systems and other key aspects of the production process. In some organizations, data is maintained off-line or uploaded from a spreadsheet ahead of a batch print. Incredibly, some companies still import data using ‘copy and paste’. And in many cases, labeling processes sit in their own operational silos, ready to be married with the product only at the final stage of the production line. In a competitive global marketplace where brand reputation is a key commodity, such archaic and disjointed approaches leave companies increasingly vulnerable to mislabeling and voluntary recall.

Yet the label remains the wrong point of focus. A broader view is required. Although it is a vital component in the production process, the label is merely one of many—a final output that is intrinsically linked, and indeed the product of, all the other variable aspects. Label design and delivery cannot, therefore, sit in isolation. It is only one aspect in a 360° process—and to meet the highest standards of accuracy, it needs to be built upon a 360° view of all the variable data components that influence its content. In the highly regulated medical device environment, these variables include product specifications, country and product-specific regulations, market destination, local language requirements, batch number and expiry dates. And the regulatory landscape, rather like companies’ product portfolios, is evolving

all the time. Systems and processes must therefore evolve with it.

Data Challenge

Despite the severe consequences of mislabeling, the label itself is not the challenge. The real challenge is the management of the data that surrounds it, and putting in place a system that can optimize the downstream benefits of integrated, centralized data across all aspects of the lifecycle. Without doubt, technology can play a major role in delivering demonstrable value across the supply chain. And in some parts of the market, it already is.

Proactive medical device companies are beginning to take a more strategic approach to the management of data and implementing fully integrated end-to-end label lifecycle management systems that capture, store and disseminate data safely, quickly and accurately. The deployment of such systems can increase efficiency by reducing the number of unnecessary manual checks, improve quality control with the use of automated validation systems throughout the lifecycle and accelerate product to market. Moreover, the use of centralized data creates a robust platform for a ‘single version of the truth’ that can be used to generate and print labels ‘just in time’—ensuring that the right information goes on the right product at the right time, every time.

And, as a belt and braces approach to reducing risk, truly holistic systems will allow for post-print verification to ensure that no errors have crept into the process at the print stage. Companies are increasingly using Vision solutions (rather than manual checks) to carry out automated audits through the print process—ensuring that approved imagery and data has been correctly printed on every label, as well as delivering complete lifecycle traceability across an end-to-end process. By integrating a Vision solution, a fully 360° system can help companies drive real value in minimizing risk, increasing productivity and maximizing ROI.

Regulatory Drivers

The drivers for change go beyond productivity and efficiency gains—though the implementation of a more flexible, transparent and accessible system for version control can undoubtedly help companies both save and make money. The evolving regulatory environment is providing a renewed catalyst for medical device firms to strengthen their production capabilities. Although final guidance from the FDA has been delayed, the imminent introduction of the Unique Device Identification (UDI) system to mark and identify medical devices will place greater pressure on the industry to improve its labeling processes—or risk product recall. The proposed rule will require manufacturers to include a plain-text version of the identifying data as well as a version encoded using AIDC technology such as 2D barcodes or RFID tags. Further, a UDI will comprise two elements; an identifier of the model and labeler of the device, and, dependent upon the class of device, the appropriate production identifier, serial number, expiration date and date of manufacture. Additionally, a new UDI will be required with every quantity change in packaging, or when the model or version of a device changes.

An already heavily scrutinized medical device environment, with numerous mandatory requirements for the presentation of variable data, is only likely to face

additional regulatory challenges—placing increased pressure on the need for more effective, integrated data management systems.

As a consequence of UDI, medical device companies will need to send the FDA reports on all of the devices they have sent into the market. It remains to be seen how well-placed companies will be to meet these requirements—though it’s likely that a number of companies’ systems will be unable to support the process. However, fully integrated, end-to-end systems that are designed to collate and sort centralized data, print, inspect and apply labels—and also provide robust audit capabilities to enable the production of comprehensive and objective documentary evidence of activity history—will undoubtedly become an invaluable tool for companies as they strive to meet the FDA’s UDI requirements. Moreover, the implementation of such systems can only help companies ensure that this potentially complicated process is as automated and seamless as it can be.

Considerations

And so, as the regulatory and economic pressures on the medical device industry increase, and as the need for operational efficiencies and cost control intensify, the sector can no longer afford to adopt such a fragmented and isolated approach to its labeling and packaging processes. The price of failure, in terms of product recalls, reputational damage and diminished profitability, is significant. The questions for organizations are clear: How effectively are you managing your data? How are you ensuring that the right information ends up on the right label at the right time, every time? Once you have generated your content, how are you making sure it is accurate? How do you set your system up in advance to ensure that it all comes together to print ‘just in time’? And finally, how do you make sure that once it’s been printed, it’s correct?

The industry will undoubtedly benefit from implementing standardized mechanisms to control its data and, as a consequence, mitigate the expensive risk of mislabeling. If companies are able to manage and structure data correctly, then all the downstream benefits will emerge for free; label designs, workflow process, inspection capabilities and audit control all flow from ensuring the right data is available to the right people at the right time. And, the efficiency gains are a natural and welcome byproduct.

Success will not happen overnight, progress will be incremental. But the technologies to give companies a 360° view of the production process are already out there. And the revolution will begin with the recognition that it’s not about the label: it’s all about the data.