

Filling Pharma's Label Management Void



Research conducted in partnership with:



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Industry survey indicates pharma's need to move towards a single, connected label management solution

By Karen Langhauser, Chief Content Director

Today's global drug manufacturers have a lot on their minds: drug pricing has reached the height of scrutiny, consumer expectations continue to rise, and regulatory compliance is stricter than ever before. Tasked with finding the perfect balance between efficiency, profitability and, most importantly, quality, many manufacturers mistakenly view product labeling as an afterthought.

Historically, printers were sold individually into different plants in different countries, which has resulted in pharma companies working with hundreds, if not thousands of fragmented printing solutions and software within the same organization. Adding to the complication, plants often use separate printing systems for labeling and direct marking tasks.

Consequently, today's pharmaceutical industry needs a single, unified solution with a standardized method of integration between each plant's label and direct marking printers, working in tangent

with the Manufacturing Execution System (MES).

The benefits of unifying and standardizing labeling processes are multiple. A modern label management process enables drug manufacturers to update label information centrally – allowing manufacturers to meet changing regulatory requirements. Standardizing the labeling process can ease transition into new markets by making it easier to roll out a uniform label production method to newly established or acquired subsidiaries. Overall, modernizing can reduce time spent on manual data entry and enable a more efficient label printing process.

Perhaps most importantly, modern label management enables drugmakers to automate quality control processes, giving them a single source of truth to verify label information. Despite modern advancement in quality control, drug recalls have increased more than 65 percent over the past ten years. In 2016, the FDA reported

77 drug recalls related to product labeling errors. With the average cost of distributing a recall notice estimated at \$8 million, labeling errors are both a dangerous and costly mistake.

Pharmaceutical Manufacturing recently partnered with NiceLabel to conduct a survey of over 100 key decision makers involved in the evaluation and purchase of label management systems in the pharma and biopharma industries. The survey results provide compelling insight in terms of where the industry stands on label management, where it is struggling, and where it needs to be.

COMPLEX LABELING LANDSCAPE

As pharma professionals quickly realize, label management is far more complex than simply printing barcodes on cartons. Most pharma companies are working with multiple products in multiple plants – 62 percent of those surveyed indicated the need to print labels across multiple locations. Adding in the challenge of label compliance for multiple markets, this culminates into what can easily be thousands of label variations.

Label change requests are another familiar struggle. Depending on in which country a company is selling products, regulations could require documenting every change in the system including new and updated

label templates. Plants have to create label formats to accommodate each system that touches the labeling process, resulting in hundreds of hard-coded label templates and long cycle times for label creation and change requests.

Consequently, pharma is working with label catalogs that are fragmented, extremely complex and consuming valuable IT resources and time.

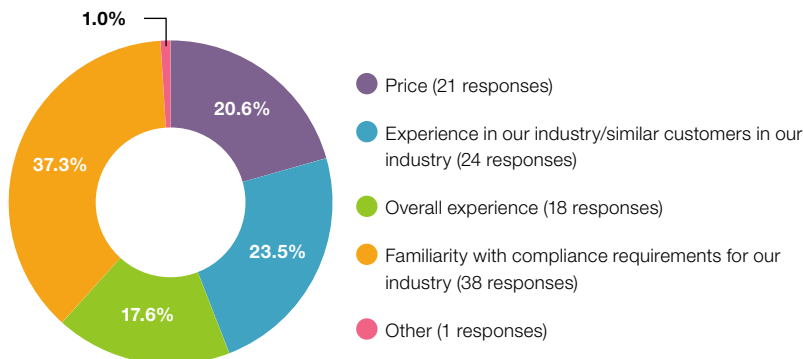
THE MODERN NEED

Survey results suggest a significant industry need for a single, centralized platform for label design, change control, printing, integration and management.

According to survey results, when asked if they currently use a standardized label management system for variable labeling processes across all manufacturing locations, only a small percentage (22.2%) of respondents reported proactively seeking out a modern labeling solution through a label management software provider. This means that 77.8 percent of companies don't have modern, digital labeling solution in place. And almost 1/3 of these companies are still using a paper-based label catalog and approval process.

When asked about the "holy grail" of label management – meaning having a label management system that is 100% integrated with MES/ERP,

WHAT ARE THE MOST IMPORTANT FACTORS FOR YOUR COMPANY WHEN SELECTING A NEW LABEL MANAGEMENT SYSTEM?



barcode and marking printers – only 14 percent of respondents can claim this accomplishment. Over 34 percent are still using separate systems to manage labeling and marking printers, and while 26.5 percent report that these printers are fully integrated with a label management system, in many cases, this integration involves a homegrown solution developed by an in-house IT team.

In order to free up manufacturing operations from being wholly reliant on IT services, there is a need for software that allows for 100 percent integration.

LABELING PRIORITIES

It is no surprise in the highly-regulated pharmaceutical industry that compliance (84%) is the most influential driver when companies decide which label management software to implement. And yet, today's pharma industry demands that drugmakers take a more proactive approach to all aspects

of manufacturing, going beyond mere compliance to find solutions that offer additional competitive advantages.

It's here that the role of standardization will continue to grow in importance, says experts at NiceLabel. A significant 35 percent of those surveyed noted standardizing labeling and marking printing as a priority when shopping for solutions. It's this standardization that will help integrate systems with MES' master data, which is key to the future of fully optimized label management.

MES integration facilitates increased automation, which is necessary for risk mitigation and error reduction. The desire to reduce labeling mistakes is also an important driver when it comes to labeling software implementation, with 83 percent of survey respondents looking for systems that reduce manual tasks and increase accuracy.

When it comes to choosing a label management

software provider, experience reigns supreme. Over 60 percent of respondents said that familiarity with industry compliance requirements and overall pharma industry experience is the most important factor when selecting a new provider.

CHALLENGES

Survey responses indicate no shortage of challenges faced by drugmakers when it comes to their current labeling systems. The leading sources of frustration were document control (35 percent) and integration with other systems, such as MES and ERP systems (24 percent). Web printing, scalability and label template design were also noted as challenges.

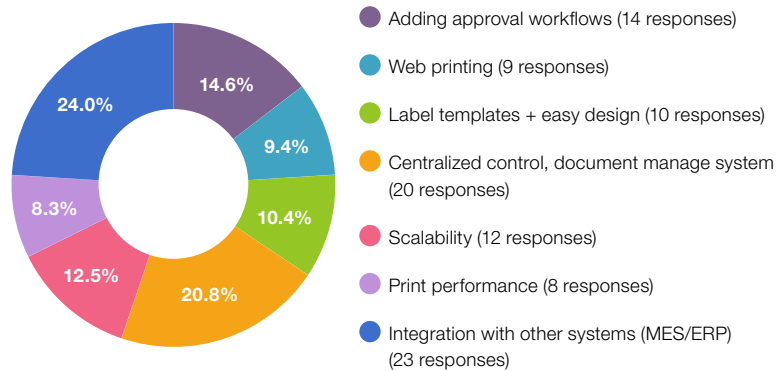
In fact, 70 percent of those surveyed are not satisfied with their current labeling system, noting that current systems are costing money indirectly in terms of IT resources and shipping delays and are simply not maximizing potential of a label management.

A standardized, fully integrated label management system can not only resolve these pain points, but can also create value in each of these areas.

THE FUTURE IS NOW

This coming November, as part of the Drug Supply Chain Security Act (DSCSA), the FDA will require pharmaceutical

WHAT IS THE BIGGEST CHALLENGE YOU ARE FACING WITH YOUR CURRENT LABELING SYSTEM?



manufacturers to code products with unique, serialized data in human and machine-readable formats. Two most commonly-used pieces of equipment to meet these DSCSA requirements are thermal inkjet printers and laser marking systems.

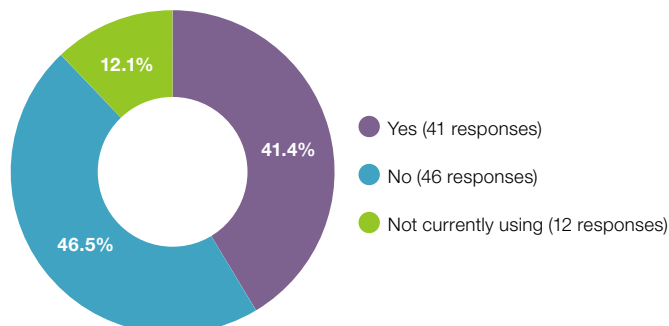
Survey results suggest that 76 percent of respondents have systems in place to meet serialization mandates – with an even split between thermal inkjet and laser solutions. And yet, 70 percent of those with these systems in place do not believe that their current labeling software equips

them to meet future serialization requirements.

The logistics involved with changing regulatory requirements can be overwhelming, and survey results indicated that pharma is making a lot of big investments in hardware but yet are missing out on the additional flexibility and benefits that could be realized with integrated systems.

Often the pharmaceutical industry sees marking and printer manufactures selling label software that is specifically built for their own printers and this software does not integrate with other marking

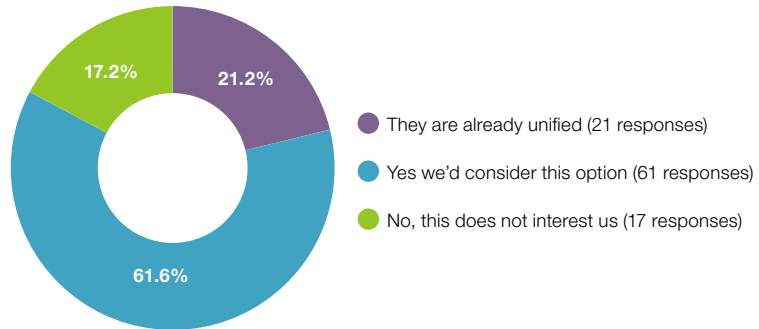
DO YOU BELIEVE THAT YOUR CURRENT LABELING SOFTWARE EQUIPS YOU TO MEET FUTURE SERIALIZATION REQUIREMENTS?



printer companies' equipment. In this scenario, working towards a unified solution is tedious and costly.

What is sorely needed in modern day pharma, where margins are tightening and mergers and acquisitions are common, is a software solution that doesn't require manufacturers to have a single printer supplier – a printer agnostic solution that can support multiple brands of direct marking and label printers. In fact, 62 percent say that they would consider unifying barcode and direct marking printers under one label management solution in order to reduce the risk of error and to enable more efficient label printing processes.

WOULD YOU CONSIDER UNIFYING YOUR BARCODE AND DIRECT MARKING PRINTERS UNDER ONE LABEL MANAGEMENT SOLUTION IN ORDER TO REDUCE THE RISK OF ERROR FROM MANUAL DATA ENTRY AND TO ENABLE MORE EFFICIENT LABEL PRINTING PROCESSES?



Many pharmaceutical companies are finding that they have simply outgrown existing labeling systems and need to put a next-generation solution in place to achieve sustainable long-term growth. And this solution – a single, unified solution with a standardized

method of integration between each plant's label and direct marking printers, working in tangent with the Manufacturing Execution System – will bring with it the advantages of increased quality control, productivity gains and cost savings. ▣

