

How Manufacturers Can Prevent Mislabeling that Causes Product Recalls: Eliminate Costly Errors with In-House Label Printing



INTRODUCTION

It's not uncommon to hear about food, beverage, and pharmaceutical product recalls in the news. Some of these recalls occur when the label content is incorrect. This can happen when the label is incomplete, obsolete, misidentified, or mismatched with a front or back label. These errors can result in reputation-damaging recalls, product liability litigation, and significant risk to human health.

For manufacturers in highly regulated industries, eliminating labeling errors is a critical and never-ending process. This brief explores how in-house digital label printing can automate label production and substantially reduce the risk of mislabeled products.



Human Error: The Primary Cause of Misapplied Labels

Many mislabeling incidents are caused by a problem that has plagued production and packaging facilities for decades: human error. Incorrectly selecting and applying the wrong roll of pre-printed labels from inventory can result in millions of dollars in product liability damages.

There are five common scenarios in which products are incorrectly labeled:

1 Packaging Line Changeover

On short-run production lines, there are multiple product changeovers each day. These changeovers require the immediate availability of labels that match the new work orders. In traditional packaging operations, staff must handpick the correct labels from stock to fulfill the order — a practice that can lead to incorrect labeling.



2 Obsolete or Changed Product Labels

Governmental regulations require that the inventory of previously-printed labels must be discarded and destroyed to avoid label mix-ups. This scenario can lead to errors as packaging staff become confused as to which labels are new and which are obsolete. Identifying and purging labels in WIP on the production floor or in the stockroom takes time and is subject to error.



3 Front and Back Labels Mismatch

This mix-up occurs when two individual labels are used on a product for front- and back-facing purposes and one label is selected and placed incorrectly.

4 Production Floor Errors

As production efficiencies demand faster label application and line changeover, packaging line staff may feel pressured to overlook small label errors, even if printed labels do not match work orders. Label content changes that operators perceive as slight or inconsequential may influence their decisions to use obsolete or misidentified labels.



5 Misapplied Clinical Trial Labels

It is critical that clinical trial products are matched to labels that are accurately printed with unique information such as batch numbers, strength/potency, directions for use, color code, expiration date, and storage requirements. Unfortunately, drug labels can appear similar to the human eye, making label mix-ups more likely.





How In-House Digital Label Printers Help Avoid Labeling Error Scenarios that Lead to Recalls

- **Packaging line changeovers:** Digital label printing reduces human error and the likelihood of label mix-ups since packaging staff can pre-print batches of labels just in time and immediately select them for use.
- **Obsolete labels:** With in-house digital label printing, an obsolete label or format can be easily and instantly eliminated from the production database while a new label design can be immediately added. Once a label format is approved, it can be printed as needed.
- **Front-and back-label mismatch:** In-house printing avoids this scenario by creating sequential front and back labels on the same label liner. As a result, both labels are matched and available for simultaneous application. Front and back labels can be printed with the same barcode or label control number, if desired, or with serialized information.
- **Production floor errors:** The risk of human error can be minimized by printing labels just-in-time at the point of use — when correctly printed labels are on hand and accurately match work orders.
- **Misapplied clinical trial products:** By pulling variable label content directly from a database in one seamless operation, in-line printers can produce labels without the need for human intervention. Each label is available to be sequentially applied to the product.



Reducing Errors and Increasing Efficiency with In-House, Just-in-Time Printing

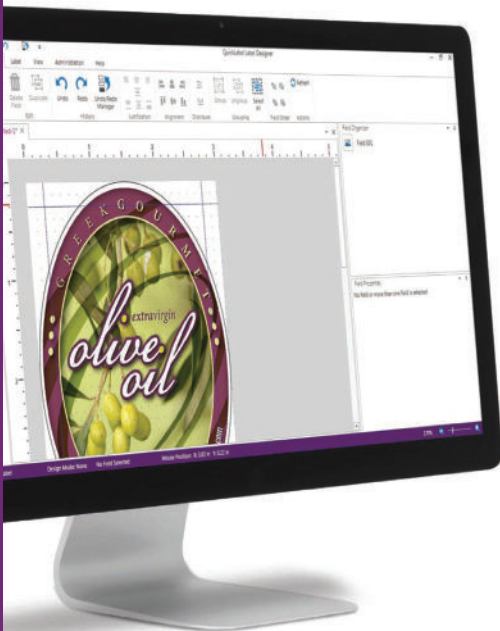
Maintaining constant supervision over labels throughout the workflow is a critical solution to avoiding labeling errors. Oversight is lost when labels are sent to a stock location and stored until a later date.

The possibility of a label mix-up is vastly reduced when labels are digitally printed on-site and utilized moments after printing, as packaging line staff never lose eye contact and custody of the labels.

When work orders are received, blank labels are printed with the correct content, including graphics, text, barcodes, and variable information. Operators can immediately load them onto the label applicator and apply them to the correct batch of products. This approach eliminates the need for label inventory and forgoes the requirement for a packaging line vision system.

Database-Driven Label Printing Eliminates Risk

Label content printed by in-house digital printers is easily controlled by software that links directly to an enterprise database. This ensures the printing of correct content, and eliminates the risk of selecting the wrong label from a stockroom shelf. The printer seamlessly produces the correct label with barcodes, descriptions, color images, and other validation content.



Touch and Print — Touchscreen Confirms Correct Label Selection

The digital label printing process is as simple as an operator walking over to the touchscreen display on the system, choosing the correct label by selecting a job name or other identifier, and then confirming the selection before printing by reviewing the thumbnail picture of the label on the touchscreen.

Alternatively, batches of labels can be automatically printed by digitally sending a batch to be printed over a network. To ensure the correct label adheres to the right product package, operators can print labels in a mobile workstation next to the production line, further reducing the possibility of human error.

Whenever important label information needs to be changed, digital printers are ready to produce updated labels on demand. With no printing plates required, there is less expense, no delays, and immediate implementation of required changes to product labels.



The Perils of Incorrect Drug Identification and Dosage

One of the most notorious mislabeling incidents occurred at Pfizer, one of the world's largest pharmaceutical companies. In March 2011, Pfizer voluntarily recalled two of its products, which were labeled incorrectly by a third-party manufacturer. Pfizer's Citalopram, a depression drug marketed as Celexa, was mislabeled as Finasteride, a drug used to treat cancer.¹

In February 2011, Qualitest Pharmaceuticals voluntarily recalled Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg 60 count, for being mislabeled as Phenobarbital, USP 32.4 mg 1000 count. Additionally, three lots of Hydrocodone were stored in the same inventory where mislabeled bottles of Phenobarbital were found.²

A case of mislabeled dosage occurred at Upsher-Smith, which recalled the Jantoven Warfarin anticoagulant drug after pharmacists found that bottles labeled as containing 3 mg tablets contained a higher dose of 10mg of Warfarin.

AstroNova Understands Your Application

Thousands of manufacturing, processing, and packaging enterprises worldwide are increasing their sales revenue and profit margins with in-house labeling. With over 50 years of innovation and expertise, AstroNova helps your business stay ahead of manufacturing and product liability risks by taking control of your labeling.

References

1. DeNoon, D. (March 28, 2011). Recall of Generic Citolapram, Finasteride, Labels of Generic Antidepressant, prostate drug switched. WebMD Health News.
2. FDA.gov. (February 5, 2011). Qualitest Pharmaceuticals Issues Voluntary, Nationwide Recall of Hydrocodone Bitartrate And Acetaminophen Tablets, USP 10 MG / 500 MG, NDC 0603-3888-20, 60 Count, Lot Numbers T150G10B, T120J10E And T023M10A And Phenobarbital Tablets, USP 32.4 MG, NDC 0603-5166-32, 1000 Count, Lot Numbers T150G10B, T120J10E And T023M10A.





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