



# How to Prevent Costly **Mislabeling and Recalls** with QuickLabel Digital Label Printing



## *Summary:*

It's not uncommon to hear about a product recall in the news. When label content is incorrect, whether the label is incomplete, obsolete, misidentified, or whether front and back labels are mismatched, products can be subject to costly, reputation-damaging recalls, and human health can be put at risk.

For manufacturers in highly regulated industries such as pharmaceuticals, medical devices, and food, investigating ways to reduce the possibility of a label mix-up is a critical and constant task. One solution is to collapse the time and handling involved in labeling products by automating the label printing process with in-house QuickLabel digital label printers making labels Just-in-Time.

## A RECENT STRING OF PHARMACEUTICAL RECALLS HIGHLIGHT THE COSTS OF LABEL MIX-UPS:

### *Examples of Product Mislabeling and Recalls*

#### **Recall Situation One**

**Incorrect drug identification:** One of the most talked about incidents is from Pfizer, one of the world's largest pharmaceutical companies. In March 2011, Pfizer voluntarily recalled two of their products which were labeled incorrectly by their third-party manufacturer.<sup>1</sup> In that situation, Pfizer's Citalopram, a depression drug marketed as Celexa, was mislabeled as Finasteride, a drug used to treat cancer.

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

# *Examples of Product Mislabeleding and Recalls*

## **Recall Situation Two**

**Incorrect dosage:** Another recent case was from Upsher-Smith, which recalled the Jantoven Warfarin anticoagulant drug called after pharmacists found that bottles labeled as containing 3mg tablets actually contained the higher dose of 10mg of Warfarin.<sup>3</sup>

~~3mg~~

# *Causes of Mislabeling*

Many mislabeling incidents are caused by a problem that has plagued packaging facilities for the last century: a human being selects the wrong roll of pre-printed labels from inventory, causing a label mix-up. There are five scenarios under which product labels are mistakenly selected:

## **Scenario One**

**Packaging Line Changeover.** On some short-run lines, there are multiple line changeovers per day. This requires the immediate availability of new labels that match the new work order. In traditional packaging operations, staff must hand pick the correct labels from stock to fulfill the order. Digital label printing reduces the likelihood of label mix-up in this scenario, since packaging staff can print batches of labels just-in-time and immediately select them for use.



# *Causes of Mislabeling*

## **Scenario Two**

**Product Labels are Obsoleted or Changed.** Governmental regulations typically require that the inventory of previously printed labels must be discarded and destroyed to avoid label mix ups. In traditional packaging operations, this scenario can lead to mislabeling 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 itself subject to the risk of error.

With QuickLabel digital label printing, an obsolete digital label format can be easily and instantly eliminated from the production database while a new label design can be easily and instantly added. Once a label format is approved, it can be printed immediately if needed.



# Causes of Mislabeling

## Scenario Three

**Front and Back Label Mismatch.** This label mix up occurs when two individual labels are used on a product, and one label is selected incorrectly. QuickLabel printers avoid this scenario by printing sequential front and back labels, on the same label liner, so that 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 serializing information.





# *Causes of Mislabeling*

## **Scenario Four**

**Production Floor Decisions.** As production efficiencies demand faster label application and line changeover, packaging line staff may feel under pressure 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. The risk of this scenario can be minimized by printing labels just in time, so that correctly printed labels are at hand.





# Causes of Mislabeling

## Scenario Five

**Misapplied Clinical Trials Labels.** In situations such as clinical trials labeling, it is absolutely critical that 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.



By printing labels and pulling variable information content directly from a database in one seamless operation, QuickLabel printers make labels without human intervention that could alter label content. Each label is then available to be sequentially applied to each product.

# How QuickLabel Digital Label Printers Help Avoid Labeling Errors that Lead to Recalls

**1 Maintaining In-House Control with Just in Time Printing.** Keeping constant supervision over labels throughout the workflow is a critical step to avoiding labeling errors. Supervision is lost when labels are sent to a stock location and stored until a later date when they are needed.



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

As a *digital* label printer, the QuickLabel Vivo! Touch produces batches of labels on-demand. When work orders are received, blank labels can be automatically printed with the correct content, including graphics, text, barcodes, and variable information. As soon as

labels are printed, operators can immediately load them onto the label applicator system and apply them to the correct batch of products. This eliminates any need for a label inventory, reduces the need for a costly vision system on a packaging line, and maintains constant line of sight supervision over labels and products to dramatically reduce the chances of a label mix-up.

# *How QuickLabel Digital Label Printers Help Avoid Labeling Errors that Lead to Recalls*

**2**

**Database-Driven Label Printing.** The label content printed by the QuickLabel printer can be controlled by software which links directly to a database. This ensures that the latest, approved information is printed for each SKU on the packaging line. There's no searching for a label with the right content, and therefore no risk of selecting the wrong label from a shelf in the stockroom. The printer presents the right label, with barcodes, descriptions, color images, and other content for validation.



# *How QuickLabel Digital Label Printers Help Avoid Labeling Errors that Lead to Recalls*

**3**

**Confirmation of Correct Label Selection via Touchscreen.** The QuickLabel label printing process can be as simple as an operator walking over to the touchscreen display on the QuickLabel Vivo! Touch label printer, choosing the correct label by selecting job name or other identifier, and then confirming the selection before printing by reviewing a thumbnail picture of the label on the touchscreen. Alternatively, batches of labels can be automatically printed by digitally sending a batch of labels to be printed over a network.

To ensure that the right label goes on the right package, operators can print labels in a mobile workstation located right next to the products that need to be labeled, further reducing the possibility of human error during the labeling process.

Whenever important label information needs to be changed, a QuickLabel printer is ready to print updated labels. With no printing plates required, there is no new expense, no delay, and no limitation in immediately implementing approved changes to product labels with a QuickLabel printer.





## REFERENCES

1 DeNoon, D. (March 28, 2011). Recall of Generic Citalopram, Finasteride, Labels of Generic Antidepressant, prostate drug switched. WebMD Health News. Retrieved May 13, 2011, from <http://www.webmd.com/depression/news/20110328/recall-of-generic-citalopram-finasteride>

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. Retrieved May 13, 2011, from <http://www.fda.gov/Safety/Recalls/ucm242398.htm>

3 FDA.gov. (February 16, 2011). Upsher-Smith Laboratories Announces The Voluntary Nationwide Recall Of Jantoven® Warfarin Sodium Tablets, USP, 3mg, Due To Mislabeled Bottles. Retrieved May 13, 2011, from <http://www.fda.gov/Safety/Recalls/ucm243811.htm>

## *QuickLabel Systems Color Label Printer Models*



Vivo! Touch



QLS-4100 Xe



Zeo!



QLS-3000 Xe



Plexo!

For More Information, Contact:



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