Technology White Paper

How Label Verification Reduces Pharmaceutical Recall Costs

MICROSCAN®

How Label Verification Reduces Pharmaceutical Recall Costs

The Drug Supply Chain Security Act (DSCSA) has been on the mind of pharmaceutical manufacturers since it was enacted in 2013, and the latest requirements are rapidly approaching. Beginning in November 2017, manufacturers will be expected to mark their products with a National Drug Code (NDC), Serial Number, Lot Number, and Expiration Date. These codes must be in both human-readable and machine-readable formats. With more than 250 pharmaceutical recalls in 2016, it is important for those throughout the pharmaceutical supply chain to benefit from the information embedded within the barcode should a recall occur. Labelers must verify that the printed barcodes comply with quality requirements per GS1 standards. Introducing a full verification system to a production line offers the potential to reduce the cost of recalls by ensuring that 100% of printed barcodes can be reliably read throughout the pharmaceutical supply chain. This white paper discusses:

- *Costs associated with product recalls;*
- *3 steps to ensuring a high-quality barcode/label;*
- *The importance of OCR/OCV for pharmaceutical packaging;*

Spencer Paullin, Microscan Systems, Inc.

Causes of Pharma Recalls

Pharmaceutical manufacturers are continuously faced with the cost of product recalls. According to Stericycle Expert Solutions' Recall Index for Q1 2017, 18.1% of the top pharmaceutical recalls were caused by mislabeling issues. Fines, brand reputation, and FDA warning letters are often the biggest concerns for pharmaceutical companies but logistical costs may increase exponentially depending on how prepared the manufacturer is to deal with the recall. Label verification systems are the best way to resolve and prevent these label and printing issues from occurring. These systems verify label data structure offline after barcode creation, offline after the final artwork has been created, and inline directly after printing or applying the code to a product.

Figure 1:
Example of a pharmaceutical packaging

Figure 2:
Example of pharmaceutical packaging

Increased regulations such as the DSCSA in the United States and the Falsified Medicines Directive (FMD) in the EU are aimed at reducing recalls and improving product traceability throughout the supply chain. According to a survey by Pharma Logistics IQ, over 50% of pharmaceutical organizations have at least started a pilot program for serialization with 28% rolling out multiple sites globally and 12.2% implementing full serialization programs. It is important for businesses to begin the move towards serialization promptly to reduce the anxiety of pushing their production lines to meet deadlines. Medical device companies have felt the true weight of product recalls after the FDA enacted the Unique Device Identifier (UDI) rule. According to a McKinsey Report, "Costs of a single non-routine quality event, like a major recall, have been as high as $600 million in medical device companies."

Three Steps for High-Quality Label Verification

Verifying pharmaceutical labels for proper data structure and print quality before products ship is a simple insurance policy against loss and fines. By implementing barcode and print quality verification systems in their operations, pharmaceutical manufacturers are able to guarantee legibility and standards compliance with precision, helping to reject noncompliant labels before they are shipped on product. Verification systems also allow pharmaceutical manufacturers to automate the process of label quality-checking, which reduces man-hours and potential human error to support leaner operations. Using inline and offline verification systems, verification systems automatically compare label features to built-in parameters, grading to standards such as GS1 and ISO 15415/15416 and providing compliance results at required tolerances for specific labeling requirements. With standards-based grading available within their equipment, manufacturers save additional time and cost associated with training staff for specific standards knowledge, allowing the verification system itself to be the standards expert.

Step 1: Verify Label Data Structure Offline after Code Creation

Ensuring the proper structure of product codes is the first step in the labeling process. Here are 9 steps to implementing a GS1-compliant barcode to meet DSCSA standards:

Figure 3:
Verifying the structure of data on labels can be accomplished using any printing method. Here, Microscan's LVS-7510 Print Quality Inspection System grades barcode quality and confirms proper data structure.

1. *Request GS1 assigned Global Trade Item Numbers (GTIN)*
2. *Assign GTINs to Products*
3. *Select a Barcode Printing Process*
4. *Select a Barcode Type*
5. *Choose a GS1-Compliant Barcode Size*
6. *Structure Barcode Data per GS1 Standards*
7. *Choose Label Substrate and Printer*
8. *Choose the Barcode Placement*
9. *Build a Barcode Quality Plan*

Each of these choices is limited by the compliance requirements that a manufacturer must meet based on their industry, type of product, or customer and legal obligations. With so many variables involved in the creation of a compliant code, and with such strict requirements per code, there are several places where errors can occur during code creation. Simply missing one GS1 application identifier, data segment, or even a single numeral can cause a code to be deemed noncompliant.

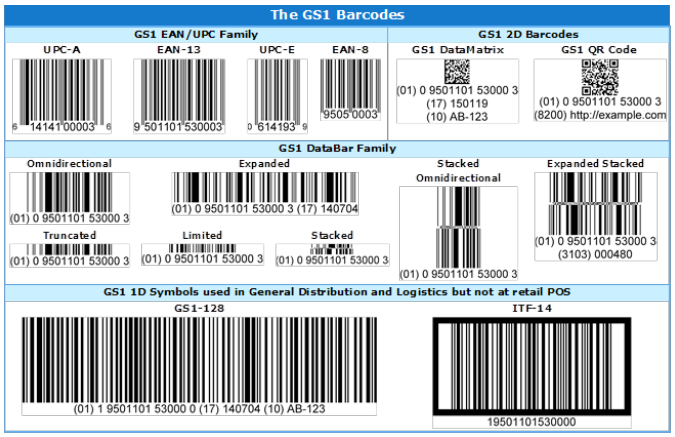

Figure 4:
Examples of GS1-compliant barcodes

Step 2: Verify Label Compliance and Readability Offline after Final Artwork

Once a code is created and verified to have the necessary structure for compliance, the code's data and appearance must remain consistent for the final label. In terms of data structure, GS1 has strict requirements for the overall size and resolution of a barcode given its type (UPC, Code 128, QR Code, etc.). In terms of legibility, ISO barcode quality requirements specify that adequate white space (quiet zone) surround the code and that the code have a consistent aspect ratio to avoid skew, in addition to a variety of other attributes. If any of

these features change from the time the code is verified, it is possible that the barcode may become noncompliant. It is critical, therefore, that the verified code remain unchanged so as not to print inaccuracies on final label stock – or worse, ship poor-quality codes on product.

Figure 5:
Microscan LVS-9585 Handheld Barcode Verifier

Step 3: Verify Label Print Quality Inline Directly after Printing or Applying to Product

Now that a perfectly-structured code has been produced and label artwork has been verified, data structure ceases to be a concern for label compliance. At this point, where the printer along with the operator selecting the correct print template are the only element affecting label production, ensuring high-quality labels is simply a matter of ensuring print quality. For the leanest labeling operations, an inline verification system should be implemented as soon as possible after a label is produced to check print quality and confirm that the correct template has been selected. An inline verification system is optimal at this stage because operations have now transitioned from performing static tests to running live production. Inline verification systems are uniquely engineered to verify label structure and quality at production speeds and can be directly installed on the line to monitor labels as they are printed.

OCR for Pharmaceutical Packaging

What is OCR?

OCR, or optical character recognition, is a verification tool that is widely used in the pharmaceutical packaging industry. Like barcode technology, OCR is a data capture and processing methodology. Its primary advantage is that it encodes information

Figure 6:
A crisp OCR font (left) is the simplest and most reliable method for decoding, while more challenging marks such as the inkjet mark on the bottom of the bottle (right) can be read using teachable OCR systems.

in a format that is both machine-readable and human-readable, while barcodes and 2D symbols are only machine-readable. OCR turns printed text characters from a digital image into a string of characters that can be decoded (read) by the system, and then moved through subsequent steps in the production process as defined by the control software. The simplest and most reliable method for optical character recognition relies on specific OCR fonts and templates that are designed for these applications. However, label verification systems incorporate teachable OCR systems that can be

Figure 7:
Microscan LVS-7510 Print Quality Inspection System

trained to recognize characters in a user-defined font – a useful feature given the wide array of available printing technologies and the range of printed characters produced by them.

The Need for OCR in Pharmaceutical

Lot codes, serial numbers, and expiration dates have become necessary in the pharmaceutical industry, which has stringent labeling requirements to help ensure consumer safety and to prevent product diversion and counterfeiting. The capability of print quality inspection systems to read these text strings reliably, at high speeds, has become indispensable in today's manufacturing environment. OCR and subsequent data retrieval help to ensure the smooth flow of information throughout the manufacturing and distribution process.

Figure 8:
Lot codes and serial numbers track pharmaceuticals throughout the supply chain

Three Common Uses of OCR in Pharmaceutical Packaging

Many manufacturers initially implement an OCR system for the sole purpose of compliance with standards, but they quickly realize the many advantages that label verification systems can bring to their packaging operations. OCR helps prevent product recalls due to labeling errors and saves cost by reducing scrapped product and minimizing downtime. With multiple proven benefits, quality monitoring by verification technology is used for a wide range of applications. Common uses of label verification OCR/OCV include verifying the presence of marked characters on products or packaging, reading date/lot codes for product traceability, and matching labels to products.

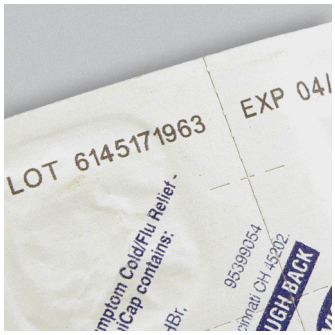

Figure 9:
OCR/OCV can be used to confirm that every product is marked with the appropriate text string before exiting the factory.

1. OCR ensures code presence and readability before products exit the factory.

One of the most basic tasks of label verification is to verify that required text strings make it onto the product or packaging. For example, inkjet printers are commonly used for marking date codes, batch codes, and expiration dates in many packaging applications, due to their ability to print variable information at very high speed. However, print quality can degrade over the course of process runs, resulting in inconsistent codes or no codes at all. Without a system in place to confirm the presence of the code, a printing fault, such as a clogged nozzle, interference from debris, or depleted ink, may affect print quality, and this error could go unnoticed until later in the process.
This results in increased downtime, costly re-runs or worse: if the product makes it out of the factory without a required code, it will need to be scrapped or recalled.

While OCR will read a code to determine its presence, another verification tool, optical character verification, or OCV, may be recommended for applications that require confirmation that a code will be readable after it leaves the plant. OCV-based inspection is most often used to verify that the printed codes will be of sufficiently high-quality to be legible throughout the supply chain in the event of a product recall – a necessity that is of particular concern in the pharmaceutical industry.

Absent or unreadable codes are unacceptable in this highly regulated industry. Label verification systems provide manufacturers with the peace of mind that their products are properly marked before they make their way into the supply chain.

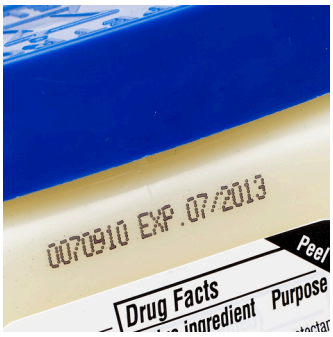

Figure 10:
Expiration date printed on a pharmaceutical package

2. OCR tracks products throughout the supply chain.

Traceability through every step of the manufacturing process is critical in any industry where manufacturers are required to comply with safety and

anti-counterfeiting regulations. Global antiterrorism measures have recently placed even more priority on product traceability. Items must be locatable at any given time within the supply chain, with clear data documenting where they originated and where they have been.

Barcodes and OCR are frequently used together to achieve maximum reliability of the data collection process. Lot codes, batch codes, expiration dates and serial numbers can be read with barcode readers to follow a product through all phases of the packaging process – from the primary product label or packaging, to carton packing, to palletizing operations. An OCR application can be configured to compare the actual text with an expected string, as defined in the database, and flag any missing or out-of-sequence serial numbers.

Reliable product tracking and data management of the production and distribution process is crucial in the event of a safety recall after the product has left the factory, and also plays an important role in preventing diversion of goods to "gray market" vendors.

3. OCR matches labels to products.

Manufacturers must accurately state the contents of an item on its label and packaging or face severe consequences, such as government-imposed penalties, costly recalls, and diminished brand perception. One of the most common reasons for product recalls – mislabeling – has serious implications for both manufacturers and consumers, ranging from customer dissatisfaction to safety risks.

Figure 11:
OCR characters can be used to make sure that the correct label is put on the container.

OCR can help to ensure that otherwise unmarked products receive the correct label during the labeling process. Products are frequently placed in containers that are initially unlabeled, and are classified as "bright stock". The only indication of what is inside the bottle or container is a text string or barcode that identifies the contents. When it is time to put a label on the bottle, the system reads the characters on it to determine which product is inside the container, then instructs the system to apply the correct label to that product. OCR is highly effective in applications where multiple character strings, such as sequential numbers, are presented to the system. In applications where all of the contents are expected to be the same, optical character verification (OCV) may be recommended. In these cases, the vision system does not read the characters, but instead verifies that they match an expected string.

Summary

Pharmaceutical manufacturers are at risk to potential fines, material waste, and loss of customers due to poor-quality labels. By implementing both in-line and off-line label verification systems, label defects can be eliminated for nearly 100 percent reliability.

Microscan has more than twenty years of experience providing OCR solutions to a broad range of industries. A global technology leader with extensive solutions for ID tracking, traceability and inspection, Microscan's line of 1D and 2D barcode readers, machine vision systems, and machine vision lighting is backed by one of the world's most robust patent portfolios and years of proven performance in the field. Microscan offers a number of products for OCR, including smart cameras, machine vision software, and 2D imagers with OCR decoding capability.

Supported by a highly skilled global integrator network, Microscan products are known and trusted by customers worldwide for their high precision and reliability in industrial automation and control applications, with solutions ranging from barcode reading, verification and machine vision.

References:

1. Stericycle® Expert Solutions. (2017). Recall Index Q1 2017. Retrieved July 14, 2017 from https://www.stericycleexpertsolutions.com/wp-content/uploads/2017/04/STCEXP-RecallIndex-Q12017-US.pdf

2. Microscan® . (2015). Three-Step Verification for Lean Product Labeling. Retrieved July 14, 2017 from http://info.microscan.com/lean-labeling

3. Microscan® . (2012). Three Ways to Enhance Pharmaceutical Packaging Lines. Retrieved July 14, 2017 from http://files.microscan.com/whitepapers/wp_pharma-ocr.pdf

4. GS1. (2015). 10 Steps to Barcode Your Product. Retrieved July 14, 2017 from https://www.gs1.org/10-steps-to-barcode-your-product

5. Ted Fuhr, Katy George, Janice Pai. The Business Case of Medical Device Quality. Retrieved July 14, 2017 from http://www.mckinsey.com

MICROSCAN®

www.microscan.com