

THE REAL COSTS OF OUTDATED PRINTING METHODS

Louis Turcotte

Industry Leader, Pharmaceutical

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Fast-changing market needs and an aging population have tremendous repercussions for pharmaceutical and medical device companies, as well as for contract manufacturing organizations (CMOs). With worldwide demand for medicines on the rise, manufacturers and CMOs alike must package more and more medicines and devices while struggling to optimize their packaging line capacity and manage changeover times and downtime.

Since each product requires its own artwork, a unique identifier, a lot number and expiration date, printing challenges add to the operational headache. Fortunately, new printing technologies provide greater flexibility when printing artwork and variable data on small print areas such as unit doses.

Because of recurring printing issues like ink spills and inconsistent print quality from one operator to the next, those who still work with outdated printing methods face frequent and unexpected downtime. They must also bear the high costs associated with the number of print mats required on most old printers, and the high waste of packaging material and ready-to-sell drugs.

What's more, according to the Stericycle Expert-SOLUTIONS Quarterly Index, printing and labeling

errors are responsible for more than half of all medical device recalls.

Pharmaceutical and medical device companies and CMOs must find a way to meet these challenges and make sure their printers provide them with the flexibility they need before reaching out to new markets and taking on new products.

This white paper guides organizations in their quest to solve print-quality issues, gain flexibility and eliminate unexpected downtime related to blister foil printing. It also:



Lists the problems and losses related to downtime



Highlights the variable costs related to aging printing methods



Compares old and new technologies



Explains the benefits related to new technologies



Explores a solution that is serialization-ready

HEALTHCARE MANUFACTURERS AND CMOs: **SAME NEED FOR FLEXIBILITY**

Although manufacturers and CMOs have different packaging realities, they share a similar need for flexibility. For example, pharmaceutical companies may package a smaller number of different medicines, but they sell them to a multitude of markets, which means that the information, artwork and variable data must be printed in several languages and follow strict regulations depending on the country of consumption. Similarly, given the nature of their business, CMOs package a lot of different medicines on the same packaging line, but they also serve a multitude

of markets. Therefore, they must be able to print different artwork and variable data for several different products and clients. CMOs need even greater flexibility.

Are current printing methods meeting this need? Or, on the contrary, are they constantly generating costly downtime? Moreover, do current printing solutions provide high-quality products to customers, while limiting complaints, late orders and delivery delays? Do they allow for print inspection and product identification control? Will their current technology enable unit-dose serialization and traceability when the time comes?

AGING PRINTING PROCESSES

The printed information for identifying medicines and devices consists of two key elements: The artwork illustrating the logo and product details, and the variable data showing the expiration date and lot number. Different processes can be used to print these, and aging printing methods are still widely used, such as inline flexographic printing, outsourced blister foil printing and embossing tools.



Image **A**: *Inline flexographic printer*

Image **B**: *Outsourced printing material in inventory*

Image **C**: *Embossed tools*

PROBLEMS AND COSTS RELATED TO DOWNTIME

Aging printing methods require more set-up time at the beginning of a batch, creating additional downtime, while recurring print-quality issues generate downtime during packaging. The solution is to use the latest printing technologies.

DOWNTIME

Planned downtime is needed and expected when changing the product format or choosing a different layout for the same product packaging. When using flexographic printers, the print mat must be changed and print tests must be performed until the quality is deemed appropriate. Only then can the packaging process start.

Changeover takes at least 30 minutes with flexographic printers. In addition, a significant amount of packaging material is lost due to printing tests, which are necessary to verify and obtain the desired product quality.

Cost: time, packaging material and products

Once packaging is underway, unexpected downtime can occur for many reasons, including packaging equipment failure, print-quality issues and ink spills. Packaging must stop as soon as a problem arises. During the downtime, some printers will need to be readjusted and/or rebooted. This means that multiple products must be printed before the print quality becomes adequate once again. Therefore, not only will the packaging material need to be discarded, but sometimes the medicines and devices will as well. Thus, depending on the monetary value of these products, the company might decide to discard them or to have operators unpack them and put them back on the packaging line.

OPPORTUNITY COST RELATED TO DOWNTIME

All this time spent adjusting the printers or fixing printing problems is time that is no longer available for packaging. This lost time cannot always be recovered during the year and may even add up to weeks of lost packaging time, in addition to wasted packaging material and products.

When flexographic printers are used to print the variable fields, mats must be changed at the beginning of each batch. As noted earlier, this changeover takes at least 30 minutes, during which packaging is stopped. If we add up all these periods of 30 minutes over a year (assuming, for instance, two batches per day and 260 days of packaging per year), it means losing eight full days of packaging each year.

If we further assume an average packaging rate of 100 cartons per minute and a \$1 profit per carton, as is common in the pharmaceutical industry, eight lost days of packaging can represent an opportunity cost of up to \$1,170,000 annually.



COSTS RELATED TO AGING PRINTING METHODS

MATERIAL COSTS

Using flexographic printers requires buying mats from a supplier. When only used to print the artwork, flexographic mats are relatively inexpensive; however, when printing the variable fields, it is common practice for companies to buy two mats for each batch in case one becomes faulty once the packaging process has started. Although this strategy helps to prevent downtime, it costs twice as much.

In comparison, outsourcing printing also generates significant costs since preprinted rolls can be 8% (for large quantities) to 40% (for smaller quantities) more expensive than blank rolls.

INVENTORY COSTS

Moreover, companies must store all this preprinted material in their inventory, which generates inventory costs of up to 25% of the total annual inventory value. Furthermore, inventory management can be a challenge when preprinted rolls with variable data remain in inventory for too long. As printed expiration dates pass, an entire supply of preprinted rolls may become unusable.

QUALITY COSTS

Just as ink spills are inevitable, several other print-quality issues frequently affect blister packaging lines. For example, one contract packager has reported that at least 60% of unexpected downtimes on his packaging lines were directly related to issues with flexographic printers. Adding up all this downtime over an entire year can represent significant opportunity costs. Also, since most packaging lines are not equipped with a vision inspection system to ensure consistent print quality, it may take a significant amount of time to discover an issue. Consequently, all medicines or devices packaged during this period will either need to be reworked or discarded, depending on which action is most cost-effective.

So how do aging printing methods compare to more recent technologies? And how do they compare when it comes to the flexibility that healthcare product manufacturers and CMOs require to provide their customers with high-quality products that are printed in high resolution and multiple colors while being carefully controlled and inspected?



PRINTING METHOD COMPARISON

FLEXOGRAPHIC PRINTERS

Flexographic printers remain popular because the purchasing price is relatively low; however, these printers generate the most downtime and the greatest number of quality problems. When there is an issue with the mat, users must order a new one, which takes time, delays packaging, and results in dissatisfied customers. Packaging is significantly dependent on the efficiency of the printer. In addition, flexographic printers offer limited flexibility on color prints, which are very complicated and extend the changeover time even more. Also, high-resolution prints are not possible with this technology.

OUTSOURCED PRINTING MATERIAL

Although it's more expensive to buy, preprinted material is also frequently used. This requires building an inventory and offers limited flexibility since the supply depends on the printing capabilities of suppliers who usually work with flexographic printers.

EMBOSSSED PRINTING MATERIAL

Embossed printing is another method that is still being used for medicine packaging. The reason is simple: It does not take much time to set up. But the problem is that some customers require variable data printed on each unit dose. In that case, embossed material is not suitable. The disadvantage of this method lies not in the costs but in the difficulty of responding adequately to customer demand.

Therefore, embossed printing material does not offer the flexibility required to meet current market demands. Companies that use it are limited to selling to pharmacies, as most hospitals require variable printing on each unit dose.

DOD PRINTERS

Drop-on-demand (DOD) is a computer-controlled printing technology. DOD printers offer high resolution and

multicolor variable data printing. With UV cured ink, they can print on almost any type of substrates. The print quality is consistent and does not depend on manual adjustments.

DOD printers do not require any mechanical adjustments between batches. Therefore, 30 minutes can be saved between every batch changeover, which increases the overall packaging capacity.

Since the purchasing price of these printers is high, calculating the ROI is important to ensure a wise investment. Nevertheless, DOD printers are particularly valuable to companies that use flexographic printers—and experience print-quality issues—and to customers who pay a premium price on preprinted material. As a result, it may be a better investment strategy for those planning to increase their packaging capacity to serve more markets in the short to medium term.

HYBRID PRINTERS

Hybrid solutions are another alternative. They consist of a flexographic functionality to print the artwork and a DOD component to print the variable data. Due to the hybrid nature of this solution, most companies will equip themselves with a vision system that only inspects the variable data. They will not inspect the fixed data printed with the flexographic mat. This results in a limited quality solution.

Hybrid solutions are more expensive than flexographic printers due to the DOD technology added to the system. The only advantage is that the same mats can be reused for multiple batches because the variable data is printed with the DOD printhead.



BENEFITS OF OPTING FOR A 100% DOD SOLUTION COMBINED WITH 100% VISION INSPECTION



Because they are computer-controlled, 100% DOD printing solutions need to be combined with a vision inspection system. This way, the vision system can validate that the printed information is accurate and the quality is satisfactory and consistent.

Most packagers who use flexographic printers and embossing tools will be satisfied with a simple visual or manual inspection at the beginning of a batch, assuming that the print quality throughout the batch will remain the same; however, print-quality issues are very common with these old technologies. Once they occur, how long will it take before the user realizes it? And how many products will have to be thrown away? Will the wasted products be counted in cartons, cases, or pallets?

Adding a vision system saves time and money and brings peace of mind. With a vision system, any problem that occurs is automatically reported and corrected.

ALL-IN-ONE PRINT AND INSPECT SOLUTION

An all-in-one printing and inspection solution is ideal because it certifies that the right information is being printed. The information is first sent to the vision system, which will then transfer it to the printer. Once the printing is completed, it is inspected, and the vision system compares the information that was sent to the printer with the information that was printed.

The vision system, therefore, is needed to guarantee the quality and accuracy of the printed data.

SERIALIZATION-READY SOLUTION



Current laws do not require unit-dose serialization for medicines; regulations only require traceability up to the carton; however, patients can only be 100% protected against counterfeit drugs if traceability reaches the level of the blister card.

Unique Device Identification (UDI) is the system used to mark and identify medical devices within the healthcare supply chain. Serialization requirements depend largely on a device's intrusiveness and risk to the patient; however, it is more and more obvious for patients, healthcare professionals and manufacturers that having a traceability system based on serialization will bring

benefits such as: quality assurance of devices or their components, protection against counterfeiting, traceability of recalled products and more efficient hospital inventory management, among others.

Serialization helps prevent the insertion of falsified medicines into the supply chain, all the way into pharmacies and hospitals. Some countries sell medicines by blister card or unit dose. This means that the serialization information is no longer there, so the product can no longer be tracked and validated. Anything that follows may become a point of entry for counterfeiters. Even today, patients are not fully protected!

Unit-dose serialization is the only solution to ensure patient safety and protect the global supply chain. Moreover, it is safe to assume that either regulations will soon require it or companies will take the initiative to implement it to protect their brand. DOD printing is the only way to attain this level of serialization.

DOD printers offer HD printing, which is necessary to print on surfaces as small as unit doses on blister cards. They also do not cause downtime, unlike flexographic printers.

CONCLUSION

DOD printing solutions offer the flexibility required by pharmaceutical and medical device manufacturers and CMOs. They minimize downtime and eliminate any associated costs.

In addition, DOD printing solutions combined with a vision system will allow unit-dose serialization, which is the only way to fully secure the healthcare supply chain for the safety of patients worldwide.

At the same time, it helps manufacturers protect their brands and reputations against counterfeiters.

Would you like to take the next step? OPTEL's experts will help you find the perfect solution for your needs and ensure the quality of the printing and labeling of your products.

For more details, contact us at:
info@optelgroup.com

