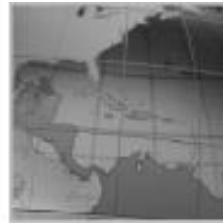


# Case Study



March 2011

## Graphic West Innovates Pharmaceutical Packaging

**Table of Contents**

Background..... 3

Opportunities in the Packaging Market ..... 3

Re-Engineering a Pharmaceutical Packaging Process ..... 4

    1) Diagnosing the Situation ..... 5

    2) Prescribing an On Demand Treatment ..... 6

    3) Developing a Digital Solution ..... 7

Commercializing the Process..... 8

InfoTrends’ Opinion..... 9

About the Author ..... 9

## Background

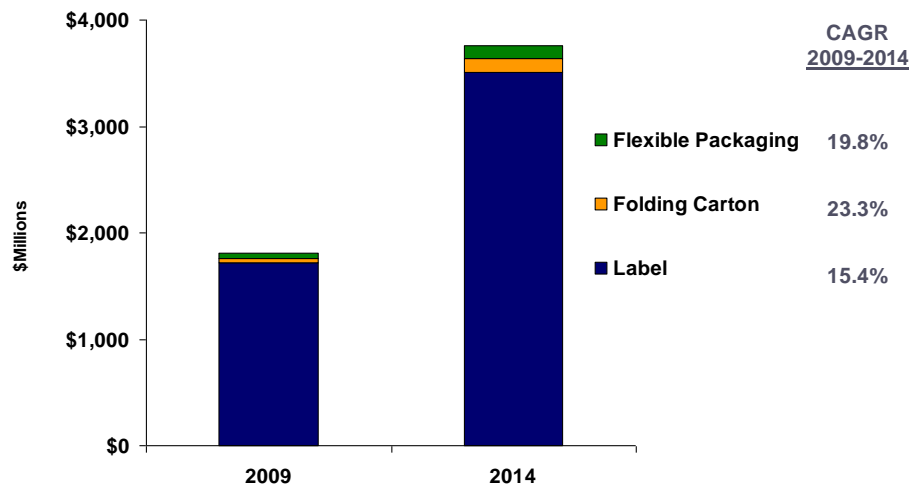
Founded in 1983, Graphic West Machinery is an international supplier of converting and gluing equipment to the box carton industry. It has locations in Australia, Denmark, the United Kingdom, and the United States. It sells new and reconditioned machinery in over 60 countries, along with customized auxiliary equipment.

Graphic West Scandinavia, a unit of Graphic West Machinery based in Denmark, is proving that innovation can come from unlikely sources. The company took the lead to develop an on-demand print packaging workflow that some drug companies and packaging printers considered to be impossible. The company identified opportunities to consolidate production steps, reduce costs, and improve efficiency in the production of medicine boxes, and took action to turn this concept into reality.

## Opportunities in the Packaging Market

Packaging represents an untapped market for digital on-demand color printing. InfoTrends projects that overall digital color printing for packaging (labels, folding cartons, flexible packaging) will experience a compound annual growth rate (CAGR) of 15.7%, rising from \$1.8 billion in 2009 to over \$3.7 billion in 2014. Although digital color printing of folding cartons represents a relatively small base of this total, revenues are expected to show a CAGR of 23.2% between 2009 and 2014. Early adapters like Graphic West are taking advantage of digital printing technology and crafting applications that significantly reduce time to market, lower waste from obsolescence, and offer enhanced efficiency to customers by moving production to a just-in-time environment that diminishes warehousing and inventory needs.

**Figure 1: Worldwide Value of Labels and Packaging Produced on a Digital Color Press**



Source: *Color Digital Printing in Packaging and Labels: A Market Assessment*, InfoTrends 2010

## Re-Engineering a Pharmaceutical Packaging Process

In an unusual set of moves, Graphic West Scandinavia engaged a drug maker, digital printing firm, and a trade finisher to develop a solid digital packaging workflow. Graphic West's Jesper Holm was the architect for this unique venture. Holm, a partner in Graphic West International, previously owned and managed Frontpac, a Scandinavian printer of microflute and cardboard packaging that serves the pharmaceutical industry. He saw an opportunity to improve the supply chain for drug packaging via on demand digital production, but none of the companies that he initially approached with his idea believed that it could be done. Holm ultimately took matters into his own hands and developed a workflow and finishing system to boost efficiency, meet the stringent security requirements of the pharmaceutical industry, and capture a new revenue stream.

**Figure 2: Jesper Holm, Graphic West partner, and the Architect of a Turn-Key GMP-Validated Print-on-Demand Pharmaceutical Packaging Workflow.**



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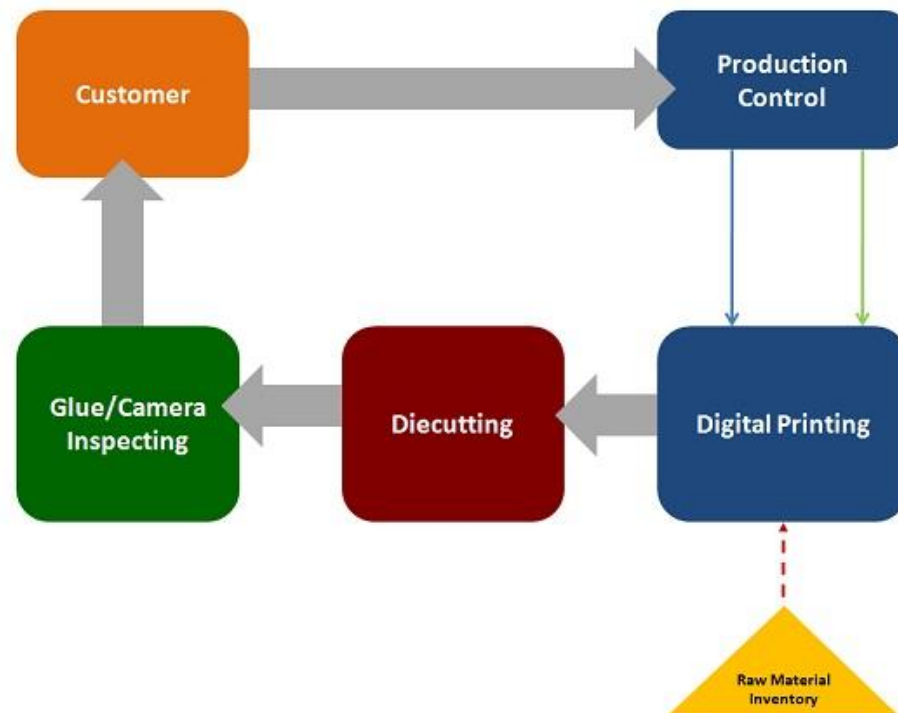
He contracted a printing firm with a Xerox® iGen4® Press, installed specially built Graphic West-owned equipment at a trade finisher, struck a deal with pharmaceutical company to print packaging on demand, and obtained global patent protection on process elements.

It took Holm two years to sell the idea, and implement the system, to his first drug manufacturing client, which is located in Denmark. Today, that system is providing the client (who wanted to remain anonymous) substantial savings per year from inventory

and waste reduction. The client was also able to eliminate 19 quality control jobs. Holm's production system reduced the number of critical inspection points required in the mandated security and validation process for medicine boxes from 21 to 7.

Holm set out to overcome bottlenecks in the production of pharmaceutical packaging with digital printing technology. Using his knowledge of the pharmaceutical packaging industry, he designed and implemented a print-on-demand packaging workflow with machinery and inspection systems that eliminates the need for storing pharmaceutical packaging in warehouses, consolidates the printing of the boxes into one step, and dramatically compresses the cycle time of mandated security and verification processes.

**Figure 3: Diagram of the Graphic West Digital Packaging Workflow**



### 1) Diagnosing the Situation

Validation and security are time-consuming, yet necessary steps in the pharmaceutical packaging supply chain. Each package must contain a batch number, a lot number, and an expiration date. This information must be printed and also provided in Braille. At the same time, a certified validation and tracing system must be in place to ensure that the correct dosage of a medicine is in the correct package.

In a typical pharmaceutical packaging workflow, boxes are printed and stored in a warehouse. When a batch of medicine goes into production, the drug company requests

the preprinted boxes from the warehouse and there is a checking procedure to make sure that the right boxes are selected. These boxes are then reprinted with lot numbers, batch numbers, and expiration dates. After this step, the boxes are checked, sent back to the drug company's filling lines, and checked again before medicine is inserted.

The validation process must be compliant with Good Manufacturing Practice (GMP) regulations, administered by governmental entities. GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production step that cannot be eliminated through testing the final product. GMP covers all aspects of production, from the starting materials, premises, and equipment to the training and personal hygiene of staff members. Detailed, written procedures are required for each process that could affect the quality of the finished product. The systems that are in place provide documented proof that correct procedures are consistently followed at each step in the manufacturing process--every time a product is made.

## **2) Prescribing an On Demand Treatment**

Jesper Holm identified opportunities to condense production steps and reduce the number of GMP inspection points by combining print on demand with specialized finishing equipment. Rather than printing, storing, and printing again, he believed that the boxes could be printed on demand via digital printing devices and finished with the validation and inspection processes occurring at the finishing stage.

"A typical order for pharmaceutical boxes is 50,000, and these are stored in a warehouse," Holm explains. "Since only 800 to 8,000 boxes are needed to fulfill a production batch, this process is a perfect fit for an on-demand model, which would save time and money."

Holm continues, "Digital printing is not really interesting to packaging manufacturers because the bottleneck is never the printing process—it is the setup times for the diecutting and gluing machines. It doesn't matter if you can print fast... everything stops at the next point."

After two years of trying to sell his concept and being told that it was impossible, Holm partnered with a print service provider with a Xerox® iGen4® Press. Holm selected the iGen4® because it had the ability to print high-quality digital output on thicker carton board, and it offered a sheet-size that could accommodate the greatest number of boxes. The printed boxes are sent to a trade finisher where Graphic West installed specialized equipment it developed for the application.

**Figure 4: Xerox® iGen4® Press**

“Graphic West owns the finishing equipment that was developed for the process and placed at the trade finisher,” Holm says. “No one believed that it could be done, so they didn’t want to make the investment.”

Having a turnkey system in place, Graphic West sold the service to a manufacturer of generic drugs. The drug maker sends it orders for boxes to Graphic West, rather than its warehouse. Graphic West can accommodate the production of up to 160 different box sizes in a 24-hour period. Each box size is customized with its own individual print and Braille application. The changeover of 160 different diecutting tools in a 24-hour cycle was the biggest challenge, Holm says. Today, change-over and setup time on diecutting equipment is less than 1 minute, thus matching the speed of the digital printing device

### **3) Developing a Digital Solution**

Holm and his partners developed an order entry system where the pharmaceutical company places orders directly to Graphic West, which are fed to the iGen4® for printing. “The customer submits the order instructions, box shape, and artwork to our system for fully automated imposition. Turnaround is 24 hours,” Holm explains.

Graphic West’s system takes the order and routes it to the box printer for printing on the iGen4®. The printed box is sent to the trade finisher for diecutting, gluing, and inspection. Holm reports that the software platform developed to fully automate order generation completed the system, and describes its development as “a unique achievement.”

A big production hurdle was reducing the setup times on diecutting and gluing machines from about 30-60 minutes to less than 1 minute. Graphic West developed specialized machinery to accomplish finishing requirements, i.e. diecutting, PDF-comparison of the Braille text, gluing, and 100% PDF comparison scan of each individual box before delivery. “We have to prove that all boxes are identical to the original PDF artwork file,” Holm elaborates. “We developed an inspection process that uses a line scanner on the gluing machine to compare the finished piece with original PDF artwork files. Only boxes that are a 100% match will pass.”

Graphic West developed a full end-to-end PDF validation process for GMP compliance using inline camera PDF recognition. According to Holm, developing and documenting a bulletproof validation process for the entire production line and getting it GMP certified was the hardest part of the entire process. The process yielded a 250-page certified GMP validation manual for rolling out the process across the pharmaceutical industry.

“Building the architecture for the process was complex,” Holm admits. “Today, however, it is running every day with no hiccups, and no one finds it complicated.”

Graphic West has obtained global patent protection on its GMP-validated production and inspection line.

The typical run length of the system is 50 to 20,000 boxes, with three to six boxes printed on the sheet. “The process yields a less expensive box because we developed a system where setup times no longer matter,” Holm says. “Digital printing is an excellent fit for this application and offers significant cost savings compared to offset printing. Producing the boxes via offset requires 500 to 600 sheets to get color right and four to five printing plates, plus storage of the boxes in a warehouse. Printing the boxes on a digital device eliminates the need for costly color adjustments, along with a great deal of production waste, time, and storage.”

He continues, “The days where offset printed boxes are better and cheaper are definitely over. Offset printing technology has no further potential for development. The future belongs to the digital printing, especially when it comes to packaging.”

### **Commercializing the Process**

With a solid GMP-validated turnkey production process established, Graphic West and Xerox will begin rolling out the application to the pharmaceutical market and others. “The best scenarios for implementing this process are applications with complexity, small box sizes, and stringent security requirements to prove authenticity and demonstrate traceability,” Holm notes. He believes application of the system will grow as drug companies pursue a personalized medicine approach.

According to a recent research report from the Tufts Center for the Study of Drug Development at Tufts University Boston, pharmaceutical companies are actively pursuing personalized medicine. The study reports that between 12% and 50% of drug companies are pursuing a personalized medicine approach at some level to provide the right drug to the right patient at the right time—an application that fits on demand packaging production.

“With personalized medicine, you’re talking about individualizing every single box,” Holm explains. “This opens up the threat of counterfeit medicine polluting the drug supply line. The workflow that we developed converts that threat into another big opportunity for us.”



## InfoTrends' Opinion

Graphic West has taken on demand packaging to a new level for secure markets. The company developed an integrated, automated on demand packaging and finishing solution that adheres to the strict verification requirements of the pharmaceutical packaging market, while also yielding significant cost savings and efficiencies.

Holm developed a turnkey application that is sure to shake up the packaging market. This is a significant development because packaging represents an untapped market for digital printing. With the workflow that Graphic West designed, this opportunity just got bigger.

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