

A person in a white lab coat is reaching for a box on a pharmacy shelf. The shelves are filled with various boxes and containers of medicine. The background is dark and out of focus.

XEIKON

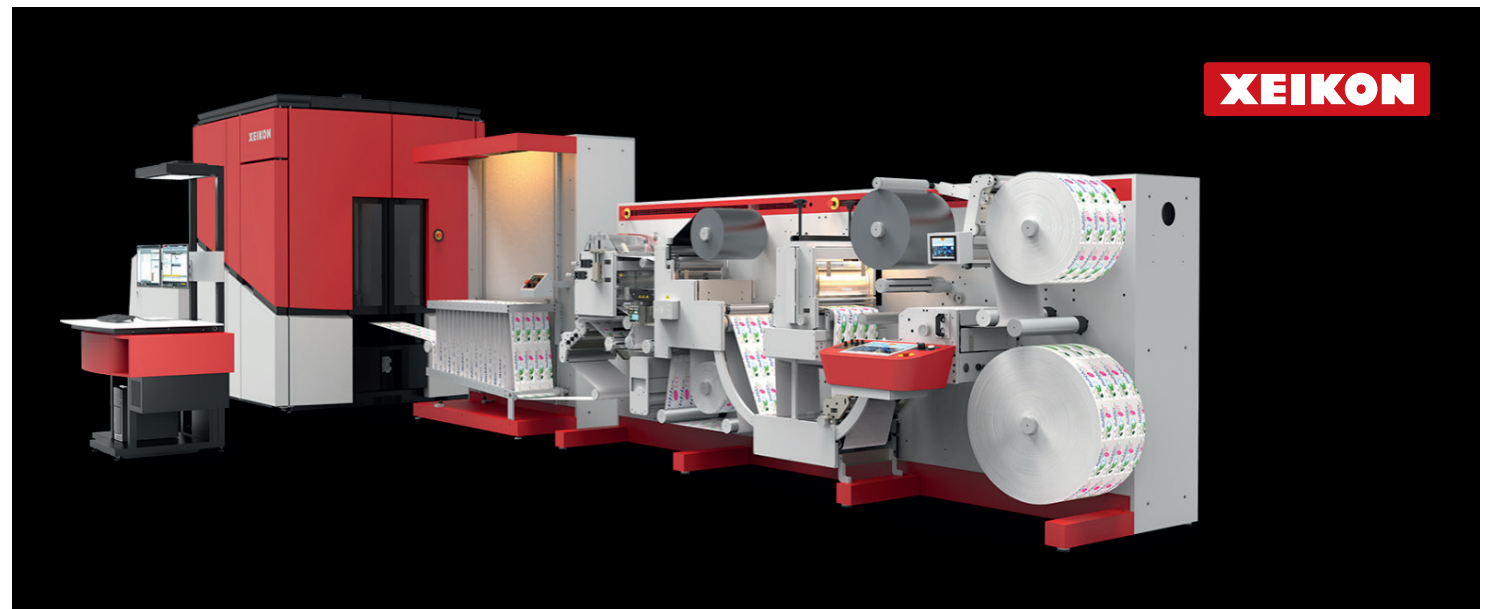
EFFICIENT SHORT-RUN PRINTING FOR PHARMACEUTICAL TRADING

A division of **Flint**Group

EFFICIENT SHORT-RUN PRINTING FOR PHARMACEUTICAL TRADING

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Section 01

THE PHARMA REIMPORTING BUSINESS



Organisations need to strive for efficiency as business objectives are becoming more complex and business processes become more demanding. Print often plays a crucial role as an enabler.

A thriving group of businesses with distinctive and critical print requirements are pharma re-importers, also labelled parallel traders. “Parallel trade” of products indicates that such trade takes place outside or in parallel with the distribution network a pharma manufacturer has established for their products at a member state of the European Economic Area (EEA).

Parallel trade benefits from price differences in the EEA countries for identical products. Therefore, parallel traders buy products at a lower price in one EEA country and then transport, repack and resell them in markets with higher prices. The parallel trader has the responsibility to assure regulatory compliance, purchasing, transport, warehousing, insurance, repackaging, quality assurance and promotion. In addition to holding a manufacturing authorisation, companies need to comply with the relevant GDP (Good Distribution Practices) for the necessary repackaging. Parallel trade is a lawful form of trade, however it is highly regulated by the European

Commission and the recipient states. It provides for more competition among pharma companies, can help solve shortages in the market and puts pressure on the prices. Affordable Medicines Europe represents Europe's licensed parallel distribution industry. It states an annual turnover of 5.5 billion for the industry. The association represents more than 120 companies in 23 EU/EEA Member States. These members account for approximately 80% of the total parallel import market volume in the EU/EEA.

Parallel traders
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Section 02

THE PRINT REQUIREMENTS

There are multiple critical functions a print solution needs to accomplish

The re-importers have the responsibility to provide statutory information for each pack of pharmaceuticals distributed. Accordingly print plays a major role in the process. Because of the different languages on packages and products, a parallel trader needs to repack the product and add the necessary information as required by local laws. The trader also needs to keep track of shipments and make sure that the information added is correct.

The nature of the business in parallel trade of pharmaceuticals is not only highly regulated, it is also very time sensitive, and opportunity and demand driven. Traders cannot plan ahead which products will be available and which markets are the most promising, consequently they need to react fast. The batch sizes do vary a lot as well, which can result in very short print runs. Batches down to 50 labels are no exception. At the same time the variety is high, with SKU's often numbering more than 3,000.

Example of pharmaceutical trade label



The mix of short and medium runs and a large number of products creates a huge workload on managing print. Installations print as many as 380 individual jobs in a day. The number of labels per job varies greatly—it can be hundreds or even thousands of labels, however more often it is a small, even very small number of labels. Furthermore, there is great variety in size and shape because all kinds of pharmaceutical products from various producers are handled, resulting in another challenge: this time in terms of finishing.

In short, there are multiple critical functions a print solution needs to accomplish. Those are:

- Short and medium print runs
- Very short turnaround time
- Closed loop integration of finishing
- Sometimes complex label structures
- Compliance to good manufacturing practices and regulations for pharma printing
- Verification and documentation of all print
- Solutions suitable for companies not experienced in print

Section 03

SETTING UP AN EFFICIENT SOLUTION

To operate cost efficiently a pharma re-importer needs a highly sophisticated production solution, in which print, converting and inspection are handled digitally, and processes are kicked off automatically to save time and labour. Yet the company's main line of business is not in print. Accordingly setting up an efficient print solution requires a consultative approach as provided by Xeikon and its Solution Services (XSS)

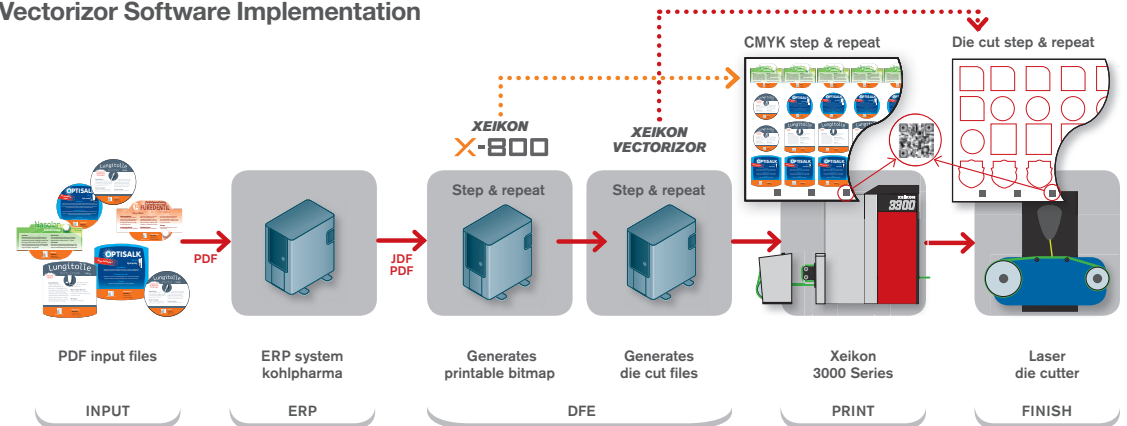
An efficient production flow starts far upstream from the Xeikon full colour digital press. The frontend of the press is able to connect to an ERP, which allows the company to track the drugs that it has re-imported and to generate the orders each day for the labels to be printed. With the help of software developers Xeikon can program solutions that interface into the companies' ordering system and can create JDF job tickets and print files. At the same time the software arranges and assembles the jobs to make best use of the press

format and the finishing set-up, considering the delivery times as well.

The print relevant data is extracted from the ERP-system and sent to Xeikon's X-800 DFE. In a step & repeat process the final imposition is created and variable data is added to the labels as required. The very low volumes require printing in multiple lanes, to take advantage of the productivity and width of the Xeikon press and to make further processing efficient. This optimisation is done by the Varilane software on the DFE.

In addition, the DFE creates a specified order ID and places data matrix codes at the begin and end of each job in a lane. Those are used for an automated set-up of the finishing and verification equipment, allowing a flow with minimal or no human interaction and constant tracking. Finally, Xeikon's Vectorizer software creates die-cut outline files for the laser die cutter and stores these on a server for access by the laser cutter. All processes are automated to take off the burden from prepress and operators and to ensure all jobs are handled correctly.

Diagram of Planned Xeikon Vectorizer Software Implementation



The Xeikon presses are scalable to handle the high volume of small to mid-size jobs effortlessly. Colour management can be automated as well, even a spot colour can be added in a fifth print station if required. Xeikon offers its Xeikon Color Services to support customers in achieving predictability and repeatability for brand colours and to match reference colours. This is crucial in pharma print where matching brand colours gives consumers confidence into a product. Various software tools, training and audits are available and can be customised for established printers and print newcomers to achieve accurate and reliable colour reproduction.

At the end of the press the rolls are slit to improve handling. Those rolls are loaded by the operator into one or multiple laser die-cutters. Using a laser die-cutter proved to be the most efficient and automated solution to create labels from the rolls of print. The laser die-cutter reads the data matrix code at the start of each job in each lane to automatically upload the correct die-cut files. The laser cutter is able to change dynamically the shapes of the labels on the web, even across different lanes. The die cutter also slits the web into final rolls according to the lanes.

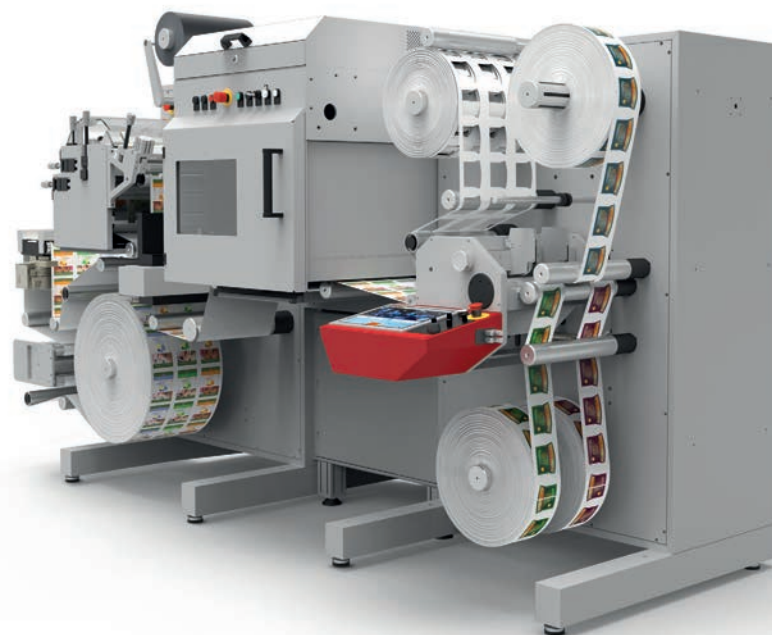
More complex designs can require the use of a dual laser die-cutter. For labels with windows the window portion is cut out with the first laser cutter unit and a clear laminate is applied. In the second laser die-cutter unit the outline of the label is cut. Based on an analy-

sis of the label requirements Xeikon Solution Services can set up these more complicated solutions as well.

As a last step an inspection rewinder is used to verify that all processes have been performed correctly. The system checks for print, cutting and substrate defects. Again,

with the data matrix codes printed at the start and end of each job, the job specifications can be retrieved by the inspection system automatically. The complete verification trail is a prerequisite for pharma printing. Based on the inspection system, Xeikon can also implement automated reprint of orders or trigger waste ejection in label application lines.

Laser die-cutter unit



HOW RE-IMPORTERS BENEFIT FROM DIGITAL PRINT



Digital print has been a great benefit to parallel traders. In many cases labels were sourced previously from third party printing companies, printed on flexo presses. The short runs required high numbers of plates, start-up waste and set-up times, making the process inefficient and slow. Waste can be considerable with several hundred metres of substrate needed per change-over on a flexo web press. With the short runs typically required the digital solution saves substrates by the factor of five.

Necessary variable information (e.g. use-by-dates, tracking codes, batch numbers) can be included in one go as well. Depending on the user's requirements, Xeikon offers a range of security and anti-counterfeit features that can be added.

As the system is fully digital, shortest runs down to a copy of "1" are possible, allowing for zero inventory for the traders – a further keystone in avoiding waste and costs. When moving to a zero-inventory solution, the space requirements for the complete production line on site are low. The whole line typically fits into the main companies' buildings.

Xeikon set up its Solution Services (XSS) group to identify and assemble the most efficient solution for customers requiring more than the standard equipment. This includes looking at the whole product and business workflow. XSS employs specialists that can draw from internal resources as well as procure external equipment or services. Accordingly, XSS is able to analyse the customers' needs to identify and assemble the best third-party equipment, software, competences and consumables. The result is a turnkey solution for the customer. This is especially helpful for users which have not produced their own print before. The high reliability of Xeikon's print systems further adds to the ease of use.

Already more than 10 installations with pharma traders exemplify that these in-house solutions offer a distinctive benefit for users to upgrade their equipment and insource print. The tight integration of print in business processes while keeping the print lines manageable leads to more pharma companies looking into insourcing of print.

These in-house solutions offer a distinctive benefit for users to upgrade their equipment and insource print

AN EXAMPLE FOR OTHER INDUSTRIES



There are many print applications and print service providers that can benefit from digital print manufacturing solutions designed by XSS, as the example for parallel traders in pharma shows. The integration of the DFE with the customer's ERP system and in turn the integration of the DFE with finishing allows for efficient production. It also allows for complete control of the process.

The installations demonstrate that Xeikon presses are designed to provide high volume printing of short runs and even variable data—which can be useful for any in-house print production. With a portfolio of toner and inkjet-based devices Xeikon can cater for a wide range of requirements.

XSS does not only offer a consultative approach, Xeikon also takes responsibility of the whole installation including services and consumables. The user benefits from having only one company to contact to set up the installation and keep it running.

A last lesson is that Xeikon can install complex production lines even for sites with limited background in print. By taking ownership of the whole production line and delivering a turnkey solution Xeikon can take digital print manufacturing into all kinds of environments requiring print. Rather than buying a printing press, users buy a solution which enables achieving the business objectives in terms of speed to market and handling an increasing diversity in jobs, at the right cost.

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The Xeikon logo consists of the word "XEIKON" in a bold, white, sans-serif font, centered within a solid red rectangular background.

ABOUT XEIKON

Xeikon is an innovator in digital printing technology. The company designs, develops and delivers web-fed digital color presses for label and packaging applications, document printing, as well as commercial printing. These presses utilize LED-array-based dry toner electrophotography, open workflow software and application-specific toners. Xeikon also manufactures basysPrint computer-to-plate (CtP) solutions for the commercial printing market. These proven CtP systems combine the latest exposure techniques with cost-efficient UV plate technology, high imaging quality and flexibility. For the flexographic market, Xeikon offers digital platemaking systems under the

ThermoFlexX brand name. ThermoFlexX systems provide high resolution plate exposure including screening, color management, as well as workflow management. All the Xeikon solutions are designed with the overarching principles of profitability, quality, flexibility and sustainability in mind. With these guiding principles and a deep, intimate knowledge of its customers, Xeikon continues to be one of the industry's leading innovators of products and solutions.

For more information,
visit www.xeikon.com

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