Mass serialisation in pharmaceuticals

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Counterfeiting of pharmaceutical products is increasing, and although the UK is not badly affected it is growing. Difficult to control, difficult to detect, lucrative and with low penalties, it provides a major danger to patients worldwide and for some third world countries counterfeiting is of plague proportions.

In November 2005, the EFPIA Anti-Counterfeiting group published a White Paper on The Anti-Counterfeiting of Medicines which focused on a 'Track and Trace System' at individual pack level to identify the entry of counterfeits into the supply chain. As a practical silver bullet in the fight against counterfeiting the technique described was the application of unique serial codes (USCs) to all packs at the patient use level. In a process similar to putting a number plate on a car, each individual pack of product has its own unique, cryptographic, non-predictive, individual identification code.

This printed information is applied to the pack during the packaging process at line speed. In addition to this random non-sequential USC, the product's identification code, batch number and expiry date are also printed and incorporated into a barcode so that it can be read automatically. If the barcode is read during manufacture and dispensing, the pharmaceutical manufacturer and dispensing chemist can automatically detect expired products, avoid dispensation errors, prevent counterfeits, fight reimbursement and tax fraud, and recall partial rather than full batches.

While groups like the FDA have encouraged the use of Radio Frequency Identification (RFID) tags for this purpose, the majority of successful applications running in the field today are using less expensive and better proven printed barcodes with additional human readable text. The data management system developed for handling the USC codes is forward compatible for use with barcode and RFID technology as it matures.

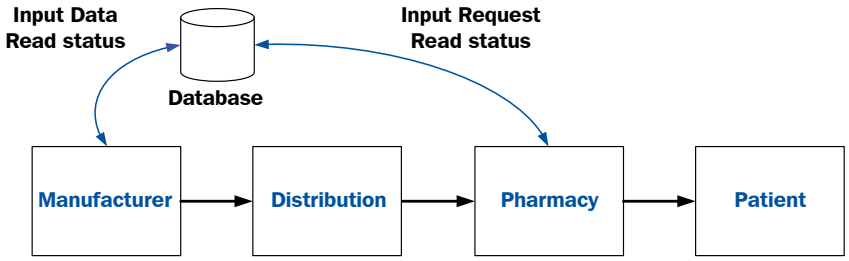
As a first step towards securing the supply chain, a 'bookend' strategy is employed where a drug product is serialised at the point of manufacture and only checked at the point of dispensing. This gives rise to the possibility that a drug authentication scheme will begin that does not initially involve all the trading partners in the supply chain.

Domino technologies print a 2D matrix code plus human readable data

Bookend authentication of a drug product

Network-based authentication services (like the proposed PILS server from EFPIA in Europe and the existing government server in Turkey) can provide drug management by allowing trading partners to automatically determine if a drug is counterfeit. If duplicates of the same serial codes are dispensed, or a false code is used, an alarm is raised alerting the pharmaceutical manufacturer and dispenser to potential counterfeits in the supply chain. Over time the pages between the bookends can be filled in and third party distributors will become involved in the process providing visibility to the movement of product through the supply chain.

The incorporation of 'parent to child' information in to the codes applied to drug units of bundles, cases, and pallets will create linkages to enable single scans of pallets or shipping cases to capture the detail of all drug units contained within.



As always, there are implications when considering mass drug product serialisation being carried out in pharmaceutical packaging halls. The sheer size of the database, generation and verification of all information and its storage, the speed of some lines, and getting this information on small packs all represent major challenges. Yet the threat from counterfeiting is so great that the introduction of such a system is imperative. As a result, mass serialisation on individual drug packs is a fact and, while demanding, it is not overwhelming to implement and can be found in successful operation in a number of packaging halls around the world today.
www.pptech.eu

New IR readable codes from Codeway

Codeway *claim to be able to further improve the security of the USC code required by the EFPIA by making it unobtrusive. Codeway maintain that having a central database logging all pack numbers naturally assists in identifying the authenticity of a particular pack, however any printed 2D code can still be copied. Codeway further state that if the counterfeiter does not know that a security code exists, it is unlikely a copy will be attempted. The answer, say Codeway, is to adopt a hidden code that can only be read with an infra-red (IR) source. A special ribbon that can be used in conventional thermal transfer printers has recently been developed that instead of transferring black ink, transfers print which is only seen using an infra-red light source. Using this IR ribbon, a hidden company logo or other security marks can be printed, along with the USC Data Matrix 2D pack coding. Dual ribbons are available that carry IR readable film and conventional back, so that both unobtrusive and human readable print can be printed at the same time.*
www.codeway.com


Hidden marking from Codeway

Domino provides support as compliance deadline looms

Domino's research indicates that up to 80% of coding devices currently installed on healthcare packaging lines in the UK will not be able to provide the speed, quality and flexibility required to meet the needs of compliance legislation. The 31 December 2010 deadline for compliance with the CIP 13 legislation in France is looming, and many manufacturers are realizing that they need to review their coding and data management procedures as a matter of urgency, say Domino.

Domino works with leading manufacturers of vision and check weighing systems to deliver complete, modular and extendable systems that comply with the current and anticipated requirements of traceability schemes worldwide, and is in ongoing discussions with bodies including GS1 and EFPIA to provide input to evolving traceability schemes based on its experience in the field.

The pharmaceutical industry specialists at Domino can provide advice on how legislation may affect coding requirements and, where necessary, offer a suitable solution. Domino's broad range of technologies for coding, include its G-Series thermal ink jet printers and D-Series laser coders, both of which are particularly suited to the demands of traceability regimes and typically include a 2D matrix code plus up to four lines of human readable data.
www.domino-uk.com

Cognex integrates track and trace into In-Sight®

Cognex is offering a comprehensive track and trace package in conjunction with their In-Sight® vision system. The In-Sight® track and trace system combines powerful Cognex code reading and verification with a prefigured job file and HMI interface. Cognex claim that this reduces set-up time and makes it easy to exchange data with third party systems that are necessary with the proposed track and trace system.

This system is GSI and FDA 21 CFR part 11 ready, and in addition to verification and reading of the USC code required by the EFPIA, is able to verify other features such as human readable codes and other packaging quality variables. The In-Sight® system is easy to install, maintain and validate, say the manufacturer, and is based upon their proven systems in the field.
www.cognex.co.uk

A ready-to-deploy data capture and verification solution for pharmaceutical and medical device manufacturers