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Tracking and Tracing Pharmaceutical Products – A Worldwide Requirement

According to the World Health Organization (WHO) up to 15 percent of all medical products in the world are estimated to be counterfeit. It is expected that fake products account for US$ 75 billion in 2010. The problem of counterfeited drugs is rising. This not only creates losses for the pharmaceutical companies but jeopardizes the health and confidence of patients taking medications. In order to combat fake drugs pharmaceutical companies are cooperating with organizations and governmental authorities to develop standards for tracking and tracing medicines globally.

E-pedigree and Serialization

An e-pedigree is an electronic record of the life cycle of a product. It records complete and accurate information about each transaction along the complex supply chain.

Serialization is the process of creating and applying a unique traceable serial number to each retail box as well as to bundles, cases and pallets. 1D, 2D bar code and RFID technology can be used to transfer product information between trading partners. For global exchange of this information common standards are mandatory (e.g. according to GS1 standards).

Technical Approach

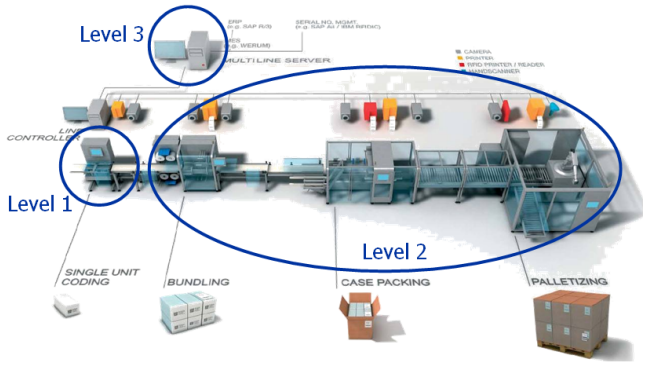
By combining expertise in engineering, industrial vision inspection and related software programming, Seidenader has developed a flexible track and trace solution for monitoring that products are sold at their defined distribution channels, and providing for conformity with legal and country-specific regulations.

Coding stations, code readers and vision systems integrated into the packaging process either on existing machines or as stand-alone solutions, provide the data for the aggregation of codes to achieve a complete pedigree of the pharmaceutical products. Seidenader T&TSolutions can be used inline or offline, as isolated application or integrated into existing IT landscape to interlink with external data bases and/or ERP/MES systems.

Depending on the set-up, serial numbers can either be transmitted to (imported by) the Seidenader system or created by the system locally. The applied data are verified via vision systems, bar code or RFID readers to track each product's pedigree. The data base maintains electronic supply chain records including records of product units lost, damaged, replaced or QA sampled.

As Seidenader is dedicated to the pharmaceutical industry, T&TSolutions comply with the required industry standards, regulations and recommendations, as well as with 21CFR Part 11, cGMP, and GAMP.

T&TSolutions can be separated into three levels as shown on the illustration:



Level 1:
Application and verification of serialized code and related human readable text on smallest saleable unit.

Typically, the Seidenader T&TSolutions on single unit level comprise a conveyor with a coding and a code verification system including inline grading functionality, a reject unit and a line controller (PC with data management software). The T&TSingleUnit is placed behind the cartoning machine or checkweigher, when used inline. The offline version allows manual handling of the boxes. Printer, reader and reject unit can also be integrated onto existing packaging machines.

Level 2 – Aggregation:
Identification / recording of the data content of units that enter the superior packaging units (bundle, case, pallet); application and verification of serialized information on corresponding superior packages.

Regarding regulatory requirements as well as automation level and process flow at the packaging line, the Seidenader T&TSolutions are extendable to bundle, case and pallet level. In cooperation with the customers Seidenader determines comprehensive solutions which consider manual or automatic processes, scanner or vision based solutions in desktop or integrated systems. As Seidenader T&TSolutions are based on a modular concept, standard components set up customized solutions. The aggregated data of all steps get added to the database of applied codes in the Seidenader T&T line controller. Rejected packaging units must be removed and can be reworked with the provided hand scanner.

Level 2 – Warehouse:
Seidenader T&TSolutions allow the integration of a warehouse. T&TWarehouse includes a workstation with a track and trace software module, a hand scanner and a label printer for commissioning. The warehouse workstation is connected to the Multi Line Server/MES/ERP at the customer's premises.

Level 3 – Data Management System for Multiple Lines:
The data management system Seidenader Multi Line Server (MLS) is a hub that interrogates with upstream systems (e.g. ERP/MES/EPCIS) and multiple downstream line controllers. At the end of the production the individual line controllers transmit batch status, quantities and pedigree related serial numbers to the MLS. A domain controller provided by Seidenader administers user and password management. If required, the Seidenader Line Management System (LMS) also provides solutions for full line control: SCADA, alarm management, access management, 21 CFR Part 11 compliance, recipe control for a production line and a complete site.

Conclusion
Although serialization provides the ability to track a product from the lab to the shelves of a distributor, these efforts are not without challenge. It is crucial for the involved stakeholders to set realistic milestones and have a good implementation plan.

Serialization projects might be seen as cost intensive hurdling, but pharmaceutical companies gain from advantages like:

- increased patient safety
- improved ability to detect and eliminate counterfeiting
- great inventory visibility
  - optimize internal stock
  - reduce out-of-stock situations
- safeguarding high value products
- ability to identify and reduce "gray market" activity and parallel trade
- simplified recalls

All in all, e-pedigree and serialization create a win-win-situation for all involved stakeholders, especially downsize fake products and therefore improve patient safety. The challenge is that everybody needs to contribute, and standards need to be defined.