

Seidenader Vision

Pharma Technology Solutions



T&TSolutions

Seidenader T&TSolutions Serialization and e-Pedigree on Pharmaceutical Packaging Lines



KÖRBER MEDIPAK
pharma packaging systems



Seidenader T&TSolutions combine various interfaces, based on open non-proprietary commercial software, to ERP/MES systems, databases, coding, code reading, grading, and material handling systems to provide a customized solution for existing as well as for new packaging lines.

Seidenader T&TSolutions track and trace from one single source

National as well as international legislation are forcing pharmaceutical manufacturers to implement complete traceability of pharmaceutical products.

Seidenader's T&TSolutions allow single item, bundle, case, and pallet serialization throughout the product packaging process in the pharmaceutical industry. With secure traceability of each item the transparency of the complete process provides advanced safety for pharmaceutical products and for the patients. Using serialization with RFID and/or 1D/2D bar coding including human readable text, the system supports anti-counterfeiting initiatives and verifies product authentication. Furthermore, T&TSolutions monitor that products are sold at their defined distribution channels and provide for conformity with legal and country-specific regulations.



Coding stations, code readers, and vision systems integrated into the packaging chain provide the data for the aggregation of codes to achieve a complete pedigree of your products ("grandparent/parent/child" relationship). The system is able to interlink with ERP/MES systems for batch data exchange. Depending on the setup, serial numbers can either be transmitted (imported) to the Seidenader system or created by the system locally for application onto the products. The flexible database system verifies the applied data via vision systems, barcode readers, or RFID readers to track each product's pedigree. It maintains electronic supply chain records including records of product units lost, damaged, replaced or QA sampled.

Seidenader T&TSolutions comply with the regulations and recommendation of 21CFR Part 11, cGMP, and GAMP.

Advantages

- Comprehensive track and trace solutions from one single source
 - ✓ Hardware incl. machine building
 - ✓ Software
 - ✓ Service
 - ✓ Documentation
- Profound experience of Seidenader in the development and implementation of automation solutions, vision systems and material handling systems
- In full compliance with worldwide existing legislations regulating track and trace concepts, and adaptable to future legal requirements
- Entire solution from machine level, multi-line to multi-site applications
- Flexible database management system securing full audit trail
- Protection against counterfeiting through highest possible transparency in the packaging process
- 21 CFR Part 11 compliant
- Standard design, modular setup, customized installation



T&TSingleUnit with up to 3 label applicators



Seidenader T&TSingleUnit

Seidenader T&TSolutions track and trace on different packaging levels

Single Unit Level

- The Seidenader T&TSingleUnit comprises a conveyor handling system with a coding system, a code verification system including inline grading functionality, a reject system and a line controller (PC with data management software). Taking given packaging line requirements into consideration Seidenader offers:
- Stand-alone solutions (inline)
 - Stand-alone solutions (offline)
 - Integrated and combined solutions

Typically, a Seidenader T&TSingleUnit is placed behind the cartoning machine or checkweigher. The offline version allows manual handling of the boxes. Alternatively, the components printer, reader and reject unit can be integrated onto existing machines, or are supplied as combined functionality as new equipment.

T&TSingleUnit with integrated check weigher



automatic T&TBundle station



T&TSolutions



manual T&TBundle station

Aggregation Level

- In regard to the automation level and process flow at the packaging line as well as to regulatory requirements, Seidenader offers various track and trace solutions on bundle, case and pallet level:
- Manual and automatic process solutions
 - Scanner or vision based infeed identification
 - Label printing and application for packaging units in desktop or integrated design
 - Scanner or vision based outfeed verification

Valid packaging codes (bundle, case, pallet) are linked to the corresponding packaging units and complement a "grandparent/parent/child" relationship. Finally the aggregated data get added to the database of applied codes in the Seidenader track and trace line controller.

Rejected packaging units must be removed and can be reworked with the provided hand scanner.



Warehouse Level

As a next step, 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. The database will be reconciled after every action at the warehouse level.

RFID (Radio-Frequency Identification)

Besides adopting barcode or Data Matrix code with human readable code solutions, also a RFID system can be applied at every level of Seidenader T&TSolutions. RFID is an automatic identification method, relying on storing and remotely retrieving data using devices called RFID tags or transponders. An RFID tag is an object that can be applied to or incorporated into a product for the purpose of identification through radio waves. Some tags can be read from several meters away and beyond the line of sight of the reader.



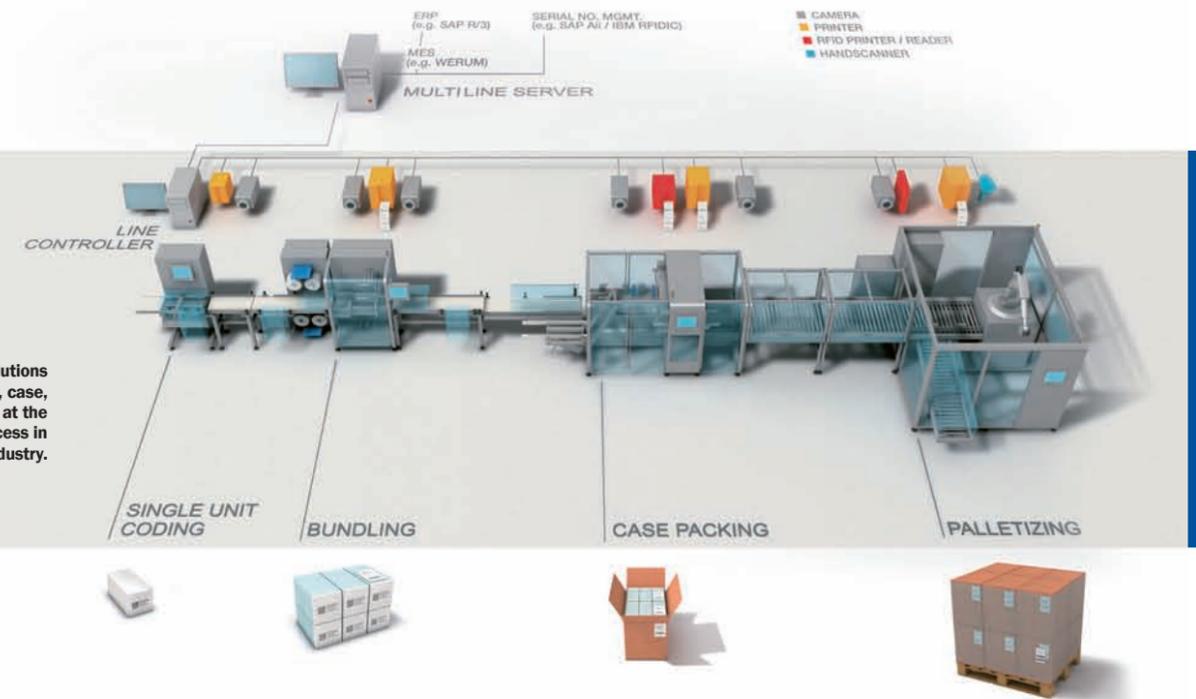
Seidenader T&TSolutions track and trace on multiple lines

Data Management System for Multiple Lines

The data management system is a Seidenader Multi Line Server (MLS) mounted in a purpose-built rack system including UPS device and VPN connection. The 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 or as required, the individual line controllers transmit batch status, quantities and pedigree related serial numbers to the Seidenader Multi Line Server.

A domain controller provided by Seidenader administers user and password management. If required, the Seidenader line management system also provides solutions for full line control: SCADA, alarm management, access management, 21 CFR Part 11 compliance, recipe control for a whole production line and a complete site.

Seidenader's T&TSolutions allow single item, bundle, case, and pallet serialization at the product packaging process in the pharmaceutical industry.



Multiple Line Server at a glance

- Central site storage for batch and serialization data
- Connection point to upstream systems (e.g. ERP, MES, serial number storage)
- Single gateway handling information/data from multiple lines
- Based on industry standard data base architecture (e.g. MS-SQL 2008, Oracle 11G)
- Possibility of batch related data conversion for export to diverse external systems
- Facilitates IT validation efforts

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Seidenader Vision is a leading specialist for vision system applications in the pharmaceutical industry. From compact inspection stations integrated in packaging or assembly machines to complete track and trace systems including data aggregation, Seidenader Vision provide engineering and implementation services.

Since we are constantly working on the improvement of our high-quality products, the texts, illustrations and figures on these pages are exemplary and not binding.

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