Serial Transparency

Together with other partners, Turck Korea has implemented a complete serialization and identification system for pharmaceutical products – from the production plant to the dispatch warehouse

The combination of RFID technology with optical sensors and camera technology provides a powerful and reliable total solution

A worldwide search is currently in progress for various ways to stop the counterfeiters of pharmaceutical products. Besides the financial loss (50 billion € a year in Germany alone), counterfeit drugs can seriously damage the health of consumers. The aim of the search is the implementation of an end-to-end serialization of pharmaceutical products within the large economic area. Serialization refers to the identification of all salable packs of medicine using serial numbers across the entire production chain. To automate the identification of the serial numbers, these are not only printed in plain text, but are also affixed as barcodes, data matrix, or RFID codes depending on the packaging unit.

Serialization in the EU by 2019
This complete serialization has to be introduced in the EU by 2019. It must be possible to identify all drug packaging without any uncertainty. Furthermore, this has to be possible at any point along the manufacturing and distribution chain. As soon as the medicine is placed in the first packaging unit (primary packaging),

such as a blister pack, they are assigned to a manufacturer and a batch. This identification must also be possible in larger packaging units such as for wholesalers or logistics providers, as well as in the drug store. Each packaging unit – from the blister and the conventional drug package (secondary packaging) that can be bought in the drug store, to bundles of several packages (tertiary packaging), right up to the complete carton or even an entire pallet of pharmaceutical products – must be identifiable completely. This kind of system is relatively complex. Several interfaces between the different systems are required, and all read and write devices must be able to access the same database in real time.

Serialization pilot project
Turck Korea together with other partners have developed a solution for Daewon Pharm, the South Korean pharmaceutical manufacturer, which could also set a precedent in Europe. The pilot project is an excellent example of automated serialization for pharmaceutical products. This involves a lot more than the actual

The major benefit of RFID compared to barcode technology: In bulk reading mode, RFID can read the entire content of a carton – up to 500 individual tags.

identification with barcodes or RFID tags: The data not only has to be available in the system at individual points but also in a network, which in the final expansion stage runs through the entire production and distribution chain. Serialization here is implemented right up to the storing of the drugs in the Daewon warehouse. In a final expansion stage, it is also possible for wholesalers and each individual drug store to be incorporated in the system and the data cloud. Besides Turck, strong partners were involved in the pilot project, who offered their experience with the parent IT infrastructure and the data connection to ERP and MES systems.

The project partners
The main contract partner in the project was the biotechnology and pharmaceutical company Hanmi, which made a major contribution in terms of know-how and experience gained from the implementation of its own RFID system. Using RFID, Hanmi revolutionized its distribution system, which also enabled an expansion of the company in the US market. Its subsidiary, Hanmi IT, had already gained relevant experience through the "Keidas" supply chain manage-

ment system, which it had developed itself and which provided a basis for the Daewon pilot project. The software can record all production management operations – from the start of production, to packaging, shipment, goods reception, right through to the sale of products. All data for this is not stored locally but is kept available and up-to-date via a data cloud for all members at every point in the production and distribution chain.

Other project partners were also involved. South Korea Telecom (SKT) provided the data cloud. The company is certified with the ISO 27001 IT security standard, and guarantees that the cloud services are reliable as well as manipulation proof and failsafe. Agathon, the consultancy firm, supported the project partners in the validation of the computer system.

Turck Korea completed the automation part of the project, in which the company developed and built complete machines which print, affix, check and read the necessary codes and tags on different packaging units. These machines communicate in turn with the Keidas system, where they provide information on the production and packaging process.

Integrated labeling machine
A labeling machine that is integrated into the production process is provided at the beginning of production in the Daewon plants. The drug packages are provided here with an RFID tag which is written with the appropriate serial number. The boxes are also provided with a 2D code and plain text print containing the same information. The correct operation of the RFID tags is checked directly in the machine, and tags are discarded if necessary. The print quality of the data matrix codes and the OCR marking is also checked.

Turck developed an RFID bulk reading machine for the project and provided it with some products from its own portfolio: Besides the inductive sensors, cordsets, power supply units, VT250-HMI controllers and BL20 fieldbus gateways, the installation also included some products from Banner Engineering - Turck's optical sensor partners - such as photoelectric sensors, emergency buttons, cameras, and vision sensors.

QUICK READ

Counterfeit pharmaceutical products present health authorities and competition regulators with a great deal of problems. For this reason, the entire production and sales chain of pharmaceutical products will be made fully transparent in the future. Together with other partners, Turck Korea introduced this so-called serialization for pharmaceutical manufacturers Daewon Pharm Co. Ltd. The cloud-based solution records the drugs from the production stage to storage in the dispatch warehouse. Depending on the requirements, barcodes, data matrix codes, either OCR text recognition or RFID are used for identification. However, all identification technologies refer to the same database in the central data cloud.

Hanmi/Turck RFID bulk reading machine

Before they are stored, the individual packs of medicine have to be combined into larger units but still have to remain identifiable in order to ensure the end-to-end tracing of the individual packs. For this reason, Turck has developed and built the RFID bulk reading machine in collaboration with Hanmi. It uses RFID to identify all packs contained in a carton even when it is closed. RFID provides a major benefit compared to barcode technology: In bulk reading mode, RFID can read the entire content of a carton – up to 500 individual tags. To do this, the packer simply places the carton in the opening of the machine and the read operation starts automatically. A total of ten RFID antennas detect all the tags in the carton. One antenna moves inside the machine in order to exclude

any duplicate readings or unread packs. Following the identification stage, the machine initiates the printing of a barcode and serial number label, which is stuck onto the outside of the carton for further identification and shipment.

Turck built both a manual version of the machine, in which employees place the cartons in the opening, as well as a conveyor belt version, in which the cartons move into the machine on a conveyor and are transported further for palletizing after identification. The compact machine is just 1.6 meters high and is very mobile.

Identification by fork lift truck

The identification of multiple cartons on a pallet is then implemented using RFID tags. The data is allocated completely. All read devices are connected to computers via Ethernet connections, which always accesses the real-time data of the pharmaceutical products via the central data cloud. This end-to-end identification encompasses the entire process, from the shipment to the drug store and finally the sale of the products to the customer.

The strength of the solution is based on the combination of the latest RFID technology with the powerful optical sensor and camera technology. Both technologies - optical identification via barcode and data matrix codes or OCR text recognition and RFID - have their strengths. The performance and process reliability of the system solution for Daewon Pharma is based on the clever combination of both identification systems. The centralization of all data in one place excludes the possibility of data synchronization errors

THE PROJECT IN NUMBERS

Duration 2014 - 2015

- 7 integrated labeling machines
- 15 monitoring panels
- 10 RFID bulk reading machines
- 2 conveyor monitoring systems
- 8 printer panels
- 1 RFID system for fork lift trucks
- 22 copies of the Edge software
- 22 BL20 Ethernet gateways with electronic modules
- 20 VT250 HMI controllers
- 20 sets of P4 vision camera and iVu vision sensor

and the other disadvantages of an asynchronous solution.

The identification
If you compare the costs of RFID and data matrix identification superficially, RFID is around ten times more expensive if you only take the costs for tags and label printing into consideration. But, as the pilot

project has clearly proven, RFID is the cheaper version with respect to an overall view of all costs (total cost of ownership), including labor costs, and equipment. The benefits of RFID are clearly in the speed and reliability of the processes: Identification is not only faster, but as many as 500 tags can be read simultaneously without having to unpack the carton. Meanwhile, optically based processes are only able to read a maximum of 200 tags simultaneously and require line of sight in all cases. However, as most recipients at the end of a logistics chain (i.e. the drug stores) do not have an RFID reading device, optical identification is used as well.

Customers benefit from project experience
The pilot project enabled Turck to gain considerable experience in the serialization of pharmaceutical products. The know-how acquired with fully automated machines - as well as the handling of projects of this magnitude in collaboration with several partners - is of particular value to both Turck and its customers. Ten subsequent projects followed in Korea alone, and discussions are in progress concerning similar projects in Europe, America and Asia.

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The RFID Bulk Reading Machine is avaliable in two variants: one for manual operation (left) and one for use on conveyor systems (above)