CASE STUDY: PHARMACEUTICAL TRACK & TRACE

cxvglobal

crestsolutions
a cxv global company

xyntek
a cxv global company

vistalink
a cxv global company

Serialisation for Compliance with Korean Regulations

The key requirement on this project was the serialisation of products to meet Korean market regulations. Korean regulations mandate manufacturers to ensure secondary packaging of pharmaceutical products are printed with an item level serial number (SGTIN) in the form of a 2D barcode or RFID, as well as the capability to hold five lines of Human Readable Text (HRT). These lines can include variable data such as lot and date codes, expiry, price, etc., and all codings must be to GS1 standards. As part of this solution, the customer also requested an off-line warehouse solution that would be capable of commissioning/ decommissioning product out of batch.

KEY RESULTS

✓ In order to minimise downtime on the customer site, a plan was put in place for the integration of the system with existing hardware to take place off-site.

✓ Following successful FAT testing at this site, the system was shipped to the customer site where the only steps left to complete were the SAT, IQ and OQ.

✓ Achieved compliance with regulations for the serialisation of packaging for the Korean market. The serialisation system was successfully installed and validated on schedule
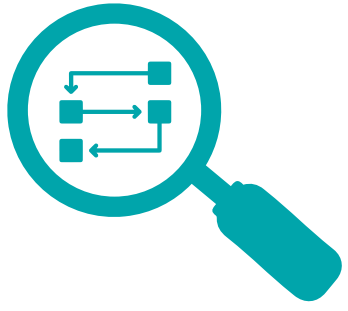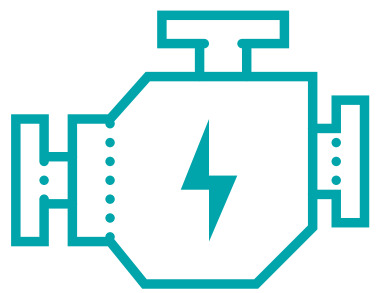
The Solution

CXV Global's team of Software and Installation & Commissioning Engineers devised a solution that comprised hardware and software from CXV Global, Antares Vision and Cognex:

- In addressing the rejection of serialised codes, the team decided to add a third camera to a typically two-camera system. The additional camera sits downstream of the checkweigher.

- The software element of the solution comprises a number of components. These include the Antares Vision Code List Manager (CLM) which communicates with the Master Tracking System (MTS) which in turn communicates with the Global Tracking System (GTS). Integration with the customer MES and ERP systems involved linking the GTS system with the MES and ERP systems.

- In order to adhere to the customer requirement for an off-line warehouse solution that would be capable of commissioning/ decommissioning product out of batch, a hand-held scanner was added to the manual station. This allows for the reading of codes, the commissioning and decommissioning of codes and taking samples for quality control.

Engineering Excellence

The complete solution runs as follows:

- The MTS receives the work order from the GTS and sets up the line devices. The CLM sends the serialised numbers to the Wolke printer and Cognex cameras and also records data back to the MTS. The first camera is positioned downstream of the printer. After a carton is printed with a serial number, this camera verifies the print quality. Next a vignette label is applied and a second camera inspects for label presence/ absence. The carton then passes over the checkweigher. If the carton is rejected at this point, it is ejected from the line and the serial number will be set as 'rejected' when the batch is completed. If the carton passes the checkweigher stage, the earlier printed serial number is commissioned by the third camera.

- This camera reports to the CLM which will accept or reject the serial number. If accepted, this number will be recorded as 'verified' and the carton will continue through the packaging line. If rejected, the carton will be ejected from the line and the serial number will be set as 'rejected' in the MTS database.

- At batch completion, reconciliation takes place and the batch is closed. This means that verified serial numbers are sent to the MTS and batch information is then communicated to the GTS. This information is then delivered to a Secure Validated Shared Folder for the customer ERP system to access. For the installation, a plan was put in place that saw integration with the hardware hardware take place in Germany so as to minimise downtime in the customer site.