In-Sight Track and Trace Helps Pharmaceutical Manufactures Meet Traceability Standards

The pharmaceutical industry is one of the most highly regulated industries in the United States. When product success could literally be a matter of life and death, quality and traceability are vitally important.

GE Intelligent Platforms QuickPanel and QuickPanel View

Traceability is the practice of understanding the flow of components and products as they move through the production process. Traceability databases will record information from labels on raw material sources and conditions, which raw material lot numbers are used in which production runs, and which packages are sent to which location. A solid traceability database allows manufacturers to quickly identify defective products and remove them from the production line if problems arise.

Traceability systems include a method to assign a unique code to parts or materials, a system to read these codes at each step of the manufacturing process, and a database to store information on the parts or materials and provide information to operators or managers as needed.

Using Track and Trace in Pharmaceutical Manufacturing

Pharmaceutical manufacturers rely on serialized labels on raw materials and final products. The Cognex In-Sight Track and Trace system allows manufacturers to streamline their traceability process and ensure database quality. The Cognex system includes vision system hardware, such as the In-Sight 5000 Vision series cameras, and VisionPro software to interpret images and interface with the system database. Cognex systems use a touch-screen interface to configure and operate Track and Trace, or the system can be integrated into an existing Windows-based vision system. Track and Trace can:

  Reads 1D and 2D barcodes and standardized code systems such as Pharmacode
  Verifies code contents for accuracy of printed text and compliance with data standards
  Examines code quality to detect degradation, misalignment, or skew

Cognex In-Sight Track and Trace is compatible with many third party products, allowing manufacturers to integrate Cognex products into their existing traceability systems.

New FDA Regulations Require More of Manufacturers

The regulations contained within FDA 21 CFR PART 11 cover electronic records, electronic signatures, and handwritten signatures. The regulation confirms that electronic records

that conform to the requirements are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper*. Cognex In-Sight Track and Trace contains several features to help companies meet the needs of FDA 21 CFR PART 11 validation:

- Password protected user authentication and multi-level user permissions
- Time stamped audit trail messages generated automatically for all user logins, system events and changes to setup parameters
- Audit messages in XML format, for conversion to compliance database or log file
- Idle timeout automatically logs out after period of inactivity

Cognex In-Sight Track and Trace allows pharmaceutical manufacturers to meet the requirements of FDA regulations and provide automatic audit trail generation. Cognex systems support applications as simple as label inspection, or as complex as company-wide traceability initiatives. Cognex vision products are easy to maintain and well-supported, meaning that a Cognex-based traceability system will maintain viability for many years to come.