Integrating Track & Trace Solutions into Existing Pharmaceutical Packaging Lines

White Paper
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Summary

Every pharmaceutical Track & Trace solution for existing systems must be customized to meet specific product line requirements, such as available space and packaging type. Out-of-the-box solutions quickly reach their limits. It is therefore advisable to develop an overall line concept before installing a Track & Trace solution in a packaging line.

Extensive engineering know-how is a key requirement for successful project implementation. Of equal importance is supplier experience in the pharmaceutical sector, in particular because of the large number of legal and quality requirements, specifically the essential GAMP certification.

Track & Trace in the Pharmaceutical Industry

The requirements with regard to production, filling, and packaging in the pharmaceutical industry are extensive. Drug quality directly impacts successful treatment of patients and counterfeit drugs present a serious risk to patients health. The share of counterfeit pharmaceuticals dispensed as published by the World Health Organization (WHO) and the US Food and Drug Administration (FDA) appears to have reached dramatic proportions. The FDA estimates that 10 percent of all drugs are counterfeit.

In recent years, many countries have established a legal framework to prevent this from happening. Unique labeling of pharmaceutical products, called serialization, combined with Track & Trace, seek to ensure that only original drugs reach the patient.

For the pharmaceutical industry, this means first of all that a technical solution must be integrated into the production and packaging of pharmaceuticals. This affects both existing lines as well as new lines that produce drugs for regulated target markets. In terms of software, unique codes must be generated and put onto products, as well as tracked by a suitable data structure. In addition, the distribution of products must be tracked so that their authenticity can be verified when they are dispensed and any irregularities can be accounted for.

This white paper looks at the challenges in terms of technical integration into packaging lines, including the design of an electronic data structure across the various packaging stages.

General Requirements for Packaging Lines

Serialization requirements typically apply to all drugs, regardless of type and packaging size. As a result, Track & Trace solutions must be integrated into a range of very different packaging lines, from blister packs in folding boxes to bags, bottles, or vials. This is compounded by the use of a myriad of different machines for filling, boxing, and palletizing. Even within a single pharmaceutical company, one line often bears no resemblance to the next one.

Serialization involves additional basic distinguishing features:

» Code carriers, e.g. 2D Data Matrix Code, EAN 128 barcode, RFID
» Coding types, e.g. GS1, PPN with drug registration number
» Accompanying documentation, e.g. Bollini (Italy)

In addition, if the information is put onto the products locally on the line, it may be necessary to verify that this has been done correctly and to check the readability of the coding.

It is therefore essential for a Track & Trace solution to be customized in accordance with local requirements. Some of the aspects to be considered are outlined below.
Integration Hurdles with Existing Systems

Pharmaceutical packaging lines are assets involving investments in the order of millions. Once put into operation, there are two basic restrictions when integrating Track & Trace on the line. Both the available space and GAMP certification of the line present major hurdles for the direct integration of machines into the existing process. To implement Track & Trace successfully in spite of these hurdles, certain aspects should be considered in advance.

**Space Requirements Demand Custom Sensor Solutions**

Putting codes onto products is a standard process on packaging lines. To verify serialization and enable linking of the various packaging levels, additional identification systems must be integrated. The key consideration for the system design is the fact that the available space and the field of view for the identification system may be restricted due to the line route. As a result, it may be necessary to install custom sensor systems consisting of a camera and lighting. A Track & Trace concept for the line should consider these restrictions in advance.

**Tracking Solutions for Production Disruptions and Sampling**

Packaging lines have been streamlined to enable ever-increasing speeds. This may result, for example, in items being in a different sequence following serialization of the sales packaging. This can be caused by, among other things, items being removed for random sampling, items being returned to the line, or transport areas being cleared.

If regulatory requirements necessitate tracking throughout the entire packaging process, or if this is desirable for business reasons, solutions such as auxiliary coding can enable unique item identification.

For example, integrating a manual data check-in and check-out system supports a correct representation of package levels when removing packaging units.

**Logical Identification During Palletizing**

It is important that aggregation only captures the boxes that were physically placed on the palette. To develop solution proposals for secure aggregation, the palletizing process and possible interference factors must be analyzed. Approaches like additional means of identification or the capture of pallet layer patterns can support the process.

**Labeling Methods**

Just as a wide variety of coding options exists, there are various technical approaches for package labeling. In addition to traditional printing methods, we find things like laser engraving or, for auxiliary coding, even UV labeling of packages. It is also essential to consider the unique properties of packaging variants (such as supple pouches or vial caps in different colors) that present challenges in terms of machine vision.
Data Aggregation
Capturing and verifying the codes is only the first step. The aggregation of data across the various packaging stages requires a special software solution. Ideally, the Track & Trace supplier uses database solutions capable of managing data dynamically in a non-volatile way. Performance is also increased through harmonized data sharing between the various reading stations.

Interfaces
There are various manufacturers with proprietary interfaces for ERP, MES or PLC. Integration with these systems can be very labor-intensive. Therefore, experience with interface integration is essential. If necessary, the Track & Trace supplier may also have to implement direct control of other hardware components, such as printers. And, finally, it must be borne in mind that the line operator also has to provide resources for integrating the Track & Trace solution into the packaging line.

GAMP Certification
When integrating the Track & Trace solution into the packaging line, industry standards must be observed. This means that GAMP certification of the components is essential. The more experience and expertise the supplier of a Track & Trace solution has in this area, the more streamlined the qualification process will be for the system operator.
How to Find the Right Partner

When looking closely at the implementation of Track & Trace for existing pharmaceutical packaging lines, numerous hurdles become evident.

This allows criteria to be formulated in order to identify a competent partner for integrating a suitable solution:

» Extensive experience with implementing identification solutions paired with engineering know-how
» Experience in the pharmaceutical industry and with GAMP qualification
» Expertise with code reading on a variety of packaging types

Looking beyond Track & Trace, these criteria can be extended as follows:

» Know-how in the field of quality inspection of packaging for one-stop shopping
» International expertise for global implementation

It doesn’t matter what challenges present themselves in relation to pharmaceutical Track & Trace – VITRONIC is your one-stop shop for sophisticated identification solutions and visual quality inspection. Worldwide.
VITRONIC is a global leader in the field of industrial machine vision headquartered in Wiesbaden, Germany. Since its foundation in 1984, the privately owned company has been offering highly innovative solutions in industrial automation, logistics and traffic technology. Today, VITRONIC is supporting customers in over 40 countries via a global network of subsidiaries, service centers and partner companies.

All of the companies’ products are developed, designed and manufactured by VITRONIC in Germany. They range from standardized to fully customized solutions.

Feel free to contact us – we look forward to hearing about your projects.

Full contact details and further information are available at www.vitronic.com