Future-proof serialisation solutions
Future-proof serialisation solutions
Flexible response to changing requirements with Track & Trace by Uhlmann

When it comes to the issue of pharmaceutical serialisation, only one thing is certain at present: its implementation. To what extent, however, is still uncertain in several countries. At the same time, numerous laws are already in force and must be heeded. This poses a major challenge for international pharmaceutical companies and service providers. On the one hand, they must be prepared to address short-term changes in legislation while, on the other hand, they do not wish to make any substantial, and possibly unnecessary, investments in advance. Furthermore, they often have to adhere to the requirements of different countries within a single packaging line. Track & Trace by Uhlmann offers pragmatic solutions to meet all serialisation requirements. Flexible standalone units, for instance, can be used for different products, and be operated within the packaging lines without extensive revalidation measures.

Basically, differentiation is made between three different types of unique product identification: the simplest being machine-readable carton identification using the global trade item number (GTIN), batch number, and expiration date. For example, this has been mandatory in France since 2011, in South Korea since 2013, and in Saudi Arabia since 2015. The second variation, serialisation, adds a unique, up to 20-digit serial number. It is generated and managed by special software. The serial numbers are recorded, forwarded to the corporate IT system, and, if necessary, transferred to an external database. This type of serialisation will be required in the European Union, for instance, presumably as of 2018.

These examples already make it clear that simply marking packs is not enough. End-to-end solutions are needed to link hardware and software to create a perfect functional system. This particularly applies to the third variation, known as tracking and tracing, e-pedigree, aggregation, or full serialisation. Each unique serial number is aggregated with that of the next larger packaging unit, authenticated, and transferred to relevant authority or government databases. Full serialisation is currently mandatory in China, India, Argentina, and Turkey. Other countries have already announced the introduction of full serialisation.

Varying national solutions give rise to uncertainty

It would be easy to grasp three different serialisation categories – were it not for national variations between the countries and the combinations of different implementation stages. In addition, serialisation specifications only apply to prescription drugs in one country, but to all pharmaceutical products in another. Some countries have drawn up a list, referred to as the "Essential Drug List", defining selected medicines, which have to be protected against counterfeiting through serialisation.
“Particularly international pharmaceutical companies and service providers are currently operating in an unpredictable environment as far as serialisation is concerned. Legislation and regulations change, deadlines are extended, and there are hardly any international standards. Every country is establishing its own system. On the basis of both our knowhow and our flexible products, we are able to offer a certain amount of security”, states Roland Längle, Manager Sales Support Software & Automation at Uhlmann Pac-Systeme GmbH & Co. KG, assessing the situation. “Especially the Uhlmann Serialisation Platform is an interesting alternative for many of our customers in preparation for various future scenarios.”

Standalone unit for maximum flexibility

The manufacturer of packaging machinery offers standalone units under the name “Uhlmann Serialisation Platform” for quick integration into existing packaging lines. Revalidation measures on a packaging line are minimal in most cases. Uhlmann offers four preconfigured variations: the smallest incorporates modules for printing and inspection; the largest additionally includes a checkweigher and applies tamper-evident labels.

Depending on legislation in the target market, the addition of a manual or automatic aggregation station may be necessary. A camera or hand-held scanner is used to record the smallest units of sale and link the data with the next larger packaging unit: the carton with the dispatch case; the dispatch case with the pallet. This is a requirement of the third category of tracking and tracing, which is already mandatory in some countries.

International contract packer opts for Uhlmann Serialisation Platform

A practical example demonstrates that the Uhlmann Serialisation Platform is a convincing response to current market requirements. “One of our customers, a contract packer, has different international pharmaceutical and biotech companies among its customers”, reports Roland Längle.

As a result, many different customer contracts are run on a single packaging line. The batches are mostly small: today for one customer, tomorrow for another customer; today for China; tomorrow for the USA, and so on. This makes the demands regarding serialisation extremely diverse and complex.

For this reason, the contract packer opted for a mobile serialisation unit including an aggregation station. The mobile unit, which went into operation in September 2014, is flexible and can be moved between all eight packaging lines. It allows the application of preprinted 1D barcode labels, as required by the Chinese market, or the printing of 2D data matrix codes directly onto the cartons using a thermal inkjet printer. A camera system within the unit checks the printing result and forwards the data to the higher-ranking Uhlmann line database system. As the company also packages for markets with mandatory aggregation requirements, a manual aggregation unit is installed downstream. An additional camera system here records each code and links it to that of the next larger packaging unit. Any influence on the line output is kept to an absolute minimum. All data is merged in the Uhlmann line controller and transferred to an Uhlmann site management system. This pools the data from several packaging lines and transmits it via an interface to the in-house SAP system of the contract packer. This solution not only allows the company to respond quickly to changes in legislation. Short-term customer decisions can also be implemented promptly.

visit our website: www.binstedgroup.com

continued
Future-proof serialisation solutions - continued

In addition to the mobile unit, the Uhmann customer is already planning the next step. A serialisation solution is to be permanently integrated into one of the lines. This is a typical course of action in Roland Längle’s opinion: “The standalone unit is a pilot project for many of our customers. It enables them to gain experience with serialisation, and with Uhmann as a supplier. Once the market requirements become more specific, they then make the next move with us.”

Many years of experience with Track & Trace

Among other things, excellent process knowledge from over 65 years of pharmaceutical packaging as well as many years of experience with tracking and tracing qualify Uhmann for such extended cooperation. The machine construction company has been keeping abreast of the issue since 2005 and has meanwhile fitted over 300 packaging lines with Track & Trace by Uhmann solutions to meet a wide variety of specifications. These not only involve Uhmann lines, but also machines from other manufacturers. Proven, high-quality components are used for printing, labelling, and inspection. These are supplemented by in-house developed software at line and site level, which is linked via interfaces to the customer’s corporate IT system as well as authority or government databases as required. Roland Längle is convinced:

“Based on the combination of hardware, software, IT expertise, project management and knowhow, we are able to offer our customers a serialisation solution that does not just meet today’s requirements. They are able to keep their options open and can respond flexibly to future specifications.”

In addition, he underlines the importance of Uhmann’s service network to customers: “Should the serialisation system malfunction, every minute counts. No serialisation, no sales. Therefore, I am of the opinion that the service network of the serialisation partner is a key aspect.” Uhmann is also well positioned in this context: the company boasts a globally operating service network, something that many other suppliers are unable to offer.

How to find the right serialisation partner

A serialisation solution is for long-term use and will be supplemented and extended systematically in the future. Therefore, it is essential to find the right partner. These central questions help to make the appropriate decision:

- Is the supplier able to supply solutions using proven systems and technologies, possibly already in use on your production line? This could bring about significant savings in the long term.
- Does the supplier have financial stability and sufficient resources to meet the immediate requirements, and to deliver a professional 24/7 service?
- How familiar is the supplier with the current regulatory requirements?
- Does the supplier have the necessary resources when it comes to the development, project planning, manufacturing, and integration of hardware and software into the packaging process?
- Does the supplier have a global service network, which is capable of prompt local support should problems arise?
- Is the supplier interested in a long-term partnership or merely after a “fast sale”?

Contact: www.uhmann.de or Tel: +49 7392 702-8277

Roland Längle
Manager Sales Support Software & Automation at Uhmann Pac-Systeme GmbH & Co. KG.

"When it comes to the issue of serialisation, many of our customers are facing major challenges. No matter whether a large, multinational enterprise or a medium-size contract packer, we are able to offer a certain amount of security on the basis of our knowhow, our experience, and our products. We offer turnkey solutions ranging from the packaging line to the customer in-house IT system, and are also in a position to manage extensive customer rollout programs through our global network of local offices".