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Track & Trace by Uhlmann



Sights set on compliance worldwide

"License to sell" is how a pharmaceutical manufacturer recently referred to compliance with diverse regulations to combat product counterfeiting. Fact is that those without a functional, country-specific compliance solution by the respective deadlines will possibly forfeit their ability to supply. In order to avoid this, pharmaceutical manufacturers should address the technical and organizational challenges related to tracking and tracing in good time. Uhlmann started working on this demanding issue back in 2005 and has fitted over 300 packaging lines with suitable automation solutions of different complexity since then. As Roland Längle, Global Product Manager Track & Trace at Uhlmann explains: "These are proving their worth in practical application and competently meet all requirements."

The goals to be attained with the introduction of tracking and tracing regulations are clear: combating the risk of counterfeit, monitoring the gray market, simplified refunding of tax revenues and health contributions, easier recall measures, and more transparent supply chains. However, Roland Längle adds: "Unfortunately, there is no master plan for the identification and tracking of medicines, but three different options: machine-readable codes, also to be referred to as French Coding, serialization as well as track and trace, also known as e-pedigree."

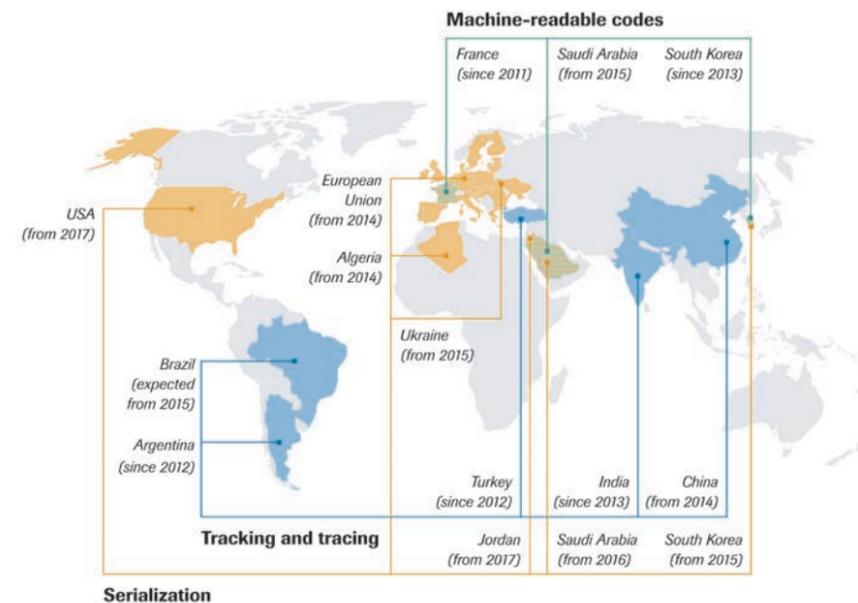
What? Where? When?

These are the key questions. What, meaning which of the three options, comes into effect where, and when? In France, marking of the carton with a machine-readable code has been mandatory since 2011. In 2013, the same ruling came into effect in South Korea and it will apply in Saudi Arabia as of 2015. In the next step, both countries require serialization. In the case of South Korea it should be realized from 2015 on and in Saudi Arabia starting in 2016. The mentioned solution will apply in the USA as of 2017. In Turkey, mandatory serialization has already been introduced in 2010 and in 2012 it has been followed by traceability from the manufacturer to the patient. The latter also applies to Argentina and it will be required in Brazil from 2015 as well as in China starting in 2014.

The implementation of the "Falsified Medicines Directive 2011/62/EU" in the European Union countries is planned within the time from 2014 to 2017. Thus, anyone involved in pharmaceutical production directed to different countries and markets is facing a major task. Here, the first step is to disentangle the confusion of affected products, national regulations, timelines, involved internal departments, external authorities as well as existing or lacking hardware and software. Then the mentioned facts have to be structured and at last, they can be dealt with step by step.

This can all be carried out on an independent basis but involves considerable time and manpower. Using a partner such as Uhlmann is an alternative. More than 65 years of experience in pharmaceutical packaging and detailed knowledge of the whole process provide the insight that is needed here. This is of vital importance in Roland Längle's opinion: "Tracking and tracing is not just a case of installing printing and inspection systems. It requires optimum tailoring of these systems to the respective packaging process and integrating them with minimum impact on line efficiency – as is the case of the numerous Track & Trace projects already successfully implemented by us."

Below: An overview of current and future requirements of different countries.



Above: Track & Trace by Uhlmann: Optimally tailored solutions integrated into Uhlmann packaging lines or machines and lines from other manufacturers may include turnkey project management if required.

Track & Trace by Uhlmann: variable functionality

Suitable high-end, tried and tested components are needed to guarantee the necessary functionality of a Track & Trace solution. Uhlmann's portfolio not only includes a broad range of printing technology and label application options but also intelligent OCR/OCV inspection systems as well as optimally coordinated printing and marking systems.

These standard components are combined to serve the respective application and can be seamlessly integrated into new as well as already existing Uhlmann machines and lines – and into lines from other manufacturers. Roland Längle refers to an exemplary integrated Track & Trace solution combining a Blister Express Center 300, Checkweigher, Stretch-banding machine S 3025 and Case packer E 4004. "All the serialization units – carton, bundle and dispatch case – are marked during the ongoing process with a unique code. Moreover, Uhlmann has a tailored solution for the many bottle packaging lines: our integrated bottle tracking system is specifically developed for the packaging of solid dose products in bottles."

Track & Trace by Uhlmann – with identical functionality and performance standards – is also available for machines and packaging lines from other manufacturers. As an example, an integrated serialization solution for the application of variable data to cartons in the ongoing cartoning process or an aggregation solution with the transfer of data to an internal or external data base. Uhlmann also offers special hardware and software solutions for manual processes: stand-alone units of different configuration levels as well as easy-to-use, manual aggregation or rework stations.

All-important factors: IT and data integrity

The key focus of Track & Trace by Uhlmann is not on the selection and implementation of suitable printing and inspection technology but on the project as a whole. Roland Längle identifies interfaces and the acquisition and transfer of data from the packaging line to higher ranking internal and external systems as critical factors. And, of course, the Uhlmann specialist places data integrity at

the top of the priority list: "Not a single code may 'get lost' or be repeated – and this applies across all lines." Uhlmann solves this by using in-house developed software for the recording, aggregation and management of serialization data from the machine to line management or even site management level. At the same time, the Uhlmann solution ensures great flexibility with interfaces open to other systems. This permits linking to existing system architectures and has already been implemented in many applications.

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Roland Längle,
Global Product Manager

Sights set on compliance worldwide continued

Professional turnkey project management also includes seamless connection to the respective corporate IT system and, if required, to an external data base such as the government data base in Turkey. Uhlmann has gained extensive experience in this field since establishing its division for Electrical Automation Projects. Over 300 successfully operating projects of various scopes have been realized for small, medium-sized and large pharmaceutical manufacturing companies.



Above: Easy-to-operate aggregation stations are available for manual processes.



“The focal issue of all Track & Trace projects is TCO – total cost of ownership. Uhlmann also provides all-round support after installation and applies its experience and broad knowledge of the packaging process at all times. On this basis, we offer our customers clear added value.”

Roland Längle, Global Product Manager Track & Trace at Uhlmann Pac-Systeme GmbH & Co. KG

Support plays a key role – worldwide

Uhlmann not only takes the immediately affected processes into account but also plays an active part in the run-up to a project. Products, target markets and deadlines are established in the context of a requirement analysis and the appropriate solutions defined. Processes, the parties involved and their scopes of responsibility are also determined: Who does what when? This matrix forms the basis of a concept, from which a master plan for implementation is derived. "The focal issue of all Track & Trace projects is TCO – total cost of ownership. Uhlmann offers all-round support from the outset and long after installation; contributes its extensive experience and broad knowledge at all times. On this basis, we offer our customers clear added value. Early involvement of a partner such as Uhlmann not only speeds up project progress but also provides a defined cost frame and guarantees the required line

efficiency from the first day of production", is how the project manager sums up the benefits.

Track & Trace by Uhlmann also involves careful observation of the market: latest findings from different pilot projects extend the pool of knowledge. The wealth of advisory skills steadily increases. An essential element of tailored Track & Trace solutions is Uhlmann's global presence. Subsidiary company offices have competent service teams to support Track & Trace projects locally and ensure smooth operation beyond today's needs in the context of a lifetime partnership.

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