PAVING THE ROAD TO COMPLIANCE:
SERIALIZATION STANDARDIZATION THROUGH OPEN-SCS

By Volker Ditscher, Business Manager Track & Trace and Martin Kühn, Vice President of Sales & Marketing

OCS
CHECKWEIGHERS

A Wipotec Company

SERIALIZATION STANDARDIZATION THROUGH OPEN-SCS

At $200 billion annually, fake pharmaceutical drugs make up the largest, global counterfeit market. While less than one percent of counterfeit drugs are sold in industrialized nations, such as the United States, 10 to 30 percent of medicines sold in developing countries are counterfeit. In some countries, this number is as high as 70 percent. The federal mandate, Drug Supply Chain Security Act (DSCSA), enacted in November 2015, attempts to combat this problem by outlining a timeline of serialization mandates that stretch all the way to 2024. It is expected that the majority of the global drug supply will fall under some type of serialization requirement by 2018.

As companies around the world implement the necessary changes to become compliant, it will add an increased level of cost, risk, and especially complexity to today's operations. Specifically, part of these mandates requires that production floor and warehouse equipment are able to exchange information with a customers' business system throughout the drug's packaging lifecycle. However, they do not indicate how this data should be exchanged. There are currently multiple vendors in the industry offering serialization solutions to accomplish this, but these systems are proprietary and are often unable to communicate with each other.

The inability for these systems to trade information prevents the interconnectivity necessary to track a package from the packaging line in the distribution center, to the pharmacy, and eventually to the patient. In order to create a supply chain that is traceable from end to end and stop the threat of counterfeits to both the pharmaceutical industry and, more importantly, to the patient, this data exchange issue needs to be at the forefront of the serialization discussion.

A consortium of pharmaceutical manufacturers and vendors are answering this call to action through a group collaboration called the Open Serialization Communication Standard (Open-SCS) working group. Its goal is to develop an industrial interoperability standard for healthcare packaging serialization regulations that improves deployment efficiency and reduces the high cost of compliance. The guidelines set forth by Open-SCS outline the following goals for serialization data exchanges:

- ⊘ **Define and simplify the base roles for each actor in the data flow to supply chain**
- ⊘ **Define the communication protocols used for each connection point**
- ⊘ **Enable greater flexibility of the serialization architecture available to the industry**
- ⊘ **Substantially reduce integration cost and delays of products from different vendors**

Through cooperation and participation across the industry, Open-SCS would be able to accomplish these open functionalities, which can be used by all of the different vendors and pharmaceutical companies in the world of pharmaceutical track and trace. Ultimately, the goal of serialization is to protect the patient; however, the pharmaceutical industry is also a business. Implementing any major change to a manufacturing facility and process needs to be analyzed and discussed, in order to ensure it is the best decision for the company. An Open-SCS architecture does offer significant benefits, but before a decision is made, it's important to understand them and why it's imperative the industry embraces this concept.

REDUCING THE RISKS
OF SUPPLY BOTTLE-NECKS

By November 2017, the DSCSA requires that all transaction data, transaction history, and transaction statements for a product must be available electronically, and the product identifier must be affixed or imprinted on the label at the product and case level. As this, as well as other global serialization deadlines approach, the need for serialization systems will grow. Unfortunately, there are not enough serialization solution vendors in the market to cover all of that demand. This leads to overloaded vendors without enough resources to service every customer. And without a standardized solution, those companies in need of resources working with one vendor will not be able to turn to a new vendor, because different vendors systems cannot operate together.

There is also the question with acquisitions and how the serialization decision is made when the companies merge. If they are each using different serialization solutions and those solutions are not utilizing open standards, which company throws away its investment? This and other scenarios begin to emerge as the industry takes a closer look at how the new world of track and trace will work in today's operations. Trough Open-SCS, the following benefits can be achieved:

Faster implementation through standardized interfaces. Another goal of developing an inter-plant serialization solution is to improve and accelerate deployment efficiency. The Open-SCS working group has developed relationships with GS1, Rx-360, ISA, and ISPE, with the hopes of reducing the implementation timeline from years to months. Through a plug-and-play set of user and functional requirements for data exchanges, the customization and modifications that can increase cost and risk as well as delay implementation would be reduced through defined standards. An integration approach where everybody already knows what to do also reduces project risks. These requirements would exist between all levels of the system's interface (equipment, operations management, and serialization supply chain) and would cover the entire requirement for healthcare serialization compliance.

Consistent functionality through validation processes. Validation of non-standardized functionalities is typically very complex. The processes need to be analyzed and verified with typical URS, GAMP and other Health and Safety Guidelines. By reducing/eliminating the interface design work, all systems would use the same terminology and speak the same "language." This will streamline the implementation by minimizing risk as well as reducing the time and man power required, which is often the biggest constrain in the hot implementation phase.

Eliminate vendor locking. In the past, vendors have not only sold the machines for printing serial numbers, but they have also provided the software and its integration into a company's IT infrastructure. As soon as such software is installed, it can be connected only with that vendor's hardware. In this scenario, it leaves the pharmaceutical company with an inability to do business with any other vendor, since the software, and often the hardware, are incompatible with each other. Should a customer one day decide to implement a level 3 site server software solution, the vendor they choose may try to take financial advantage and competitive bidding will get very difficult. Also, in this scenario, integrating multiple site servers will complicate operations, as managing two orders and moving production from one server to another. If there is ever a duplication of features, this could ultimately lead to major errors when data is sent to the wrong packaging lines. Also, Open-SCS should put a pharmaceutical manufacturer in a situation that allows them to follow a best breed approach for different product presentations (carton, bottle, pouch, etc.) and pick the most suitable vendor for the particular application.

Overall, in a business like the pharmaceutical industry, where there is constant change, systems need to be flexible enough to accommodate or to follow those changes, without adding additional challenges along the way. Open-SCS offers this flexibility while also improving employment efficiency and reducing the high cost of compliance with aggressive global regulations.

TQS: OPEN XML-INTERFACES FOR SECURE AND DEPENDABLE DATA TRANSPORT

No matter what your current IT structure looks like, you must always integrate the required or generated Track & Trace data. The following applies: The lower the number of optional modules to be installed, the better the system will operate.

TQS relies on the use of open XML standard interfaces, avoiding the creation of any proprietary island solutions. The TQS Line Manager gives you the lowest possible IT overhead. The job order data can be input directly into the machine. The Line Manager runs on any TQS module on the line and can easily and conveniently connect to a variety of Level 3 providers.

The core of the Line Manager is the production database which stores the data during the production operations. In the event of a temporary server and network infrastructure failure, the production line is secured by means of a local buffer memory. The permanent data storage is performed only in the Level 3 systems.

EASY INTEGRATION THROUGH A HIGHLY FLEXIBLE SOFTWARE SOLUTION DISTINGUISHED BY OPEN INTERFACES
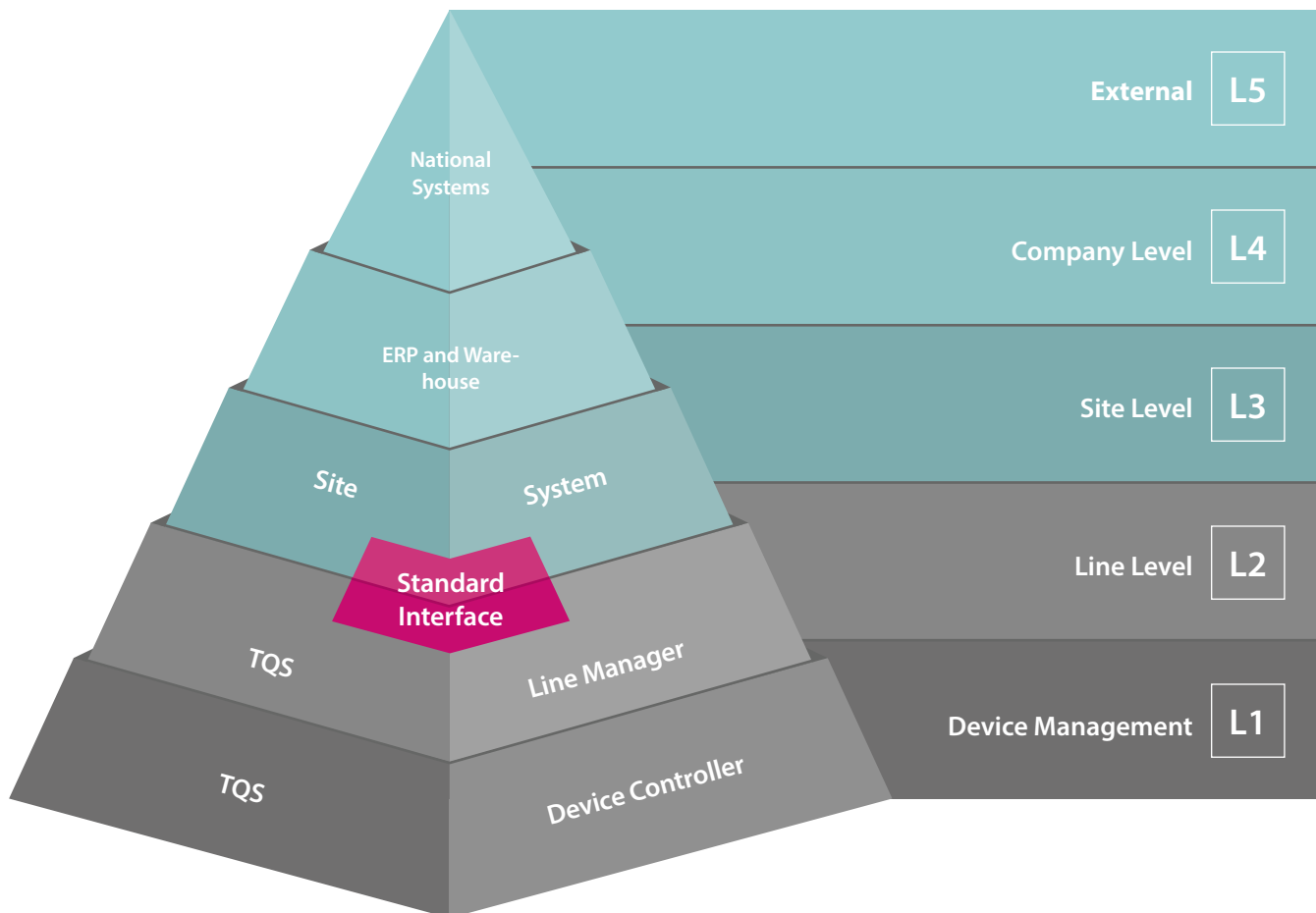
THE GUARANTEE FOR PROCESS AND PRODUCT SAFETY

OCS is a solution provider to GS1 Germany and also a voting member of the GS1 Global Healthcare Solution Provider Network. We actively participate in joint ventures with the major pharmaceuticals and implement, the relevant targets and modifications regarding serialization and aggregation.

OCS is a member of the Open SCS Working Group. This indicates our commitment to flexible options for the integration in existing production infrastructures, as well as to the philosophy of open and standardized connections to higher-level systems.

TQS-SP
Single Pack Serialization

TQS-HC-A
Tamper-Evident/Serialization/Weighing

TQS-BP
Bundle Pack Aggregation

TQS-CP
Case Aggregation

Headquarters:

OCS Checkweighers GmbH
Adam-Hoffmann-Str. 26
67657 Kaiserslautern
Germany

T +49.631.34146-0
F +49.631.34146-8690
info.ww@ocs-cw.com
www.ocs-cw.com

OCS Checkweighers, Inc.
825 Marathon Parkway
Lawrenceville, GA 30046
United States of America

T +1.678.344-8300
F +1.678.344-8030
info.usa@ocs-cw.com
www.ocs-cw.com

A Wipotec Company