TRACK & TRACE SYSTEMS FOR SERIALIZATION AND AGGREGATION

→ BY **PERE VILANOVA**, GRIFOLS

GRIFOLS' SERIALIZATION AND AGGREGATION SYSTEMS AND PROCESS MAKE IT POSSIBLE TO CARRY OUT **TRACK AND TRACE OPERATIONS AT VIRTUALLY ANY MOMENT**; NOT ONLY IN THE SUPPLY PROCESS, BUT ALSO **DURING THE LOGISTIC AND MARKETING PROCESSES**

The ability to track & trace pharmaceutical product in the distribution channel has always been a regulatory imperative, but those regulations are evolving and becoming more sophisticated to improve drug safety and the threat of counterfeits in the supply chain. In spite of the regulatory burden, the ability to accurately track and trace product and manage the disposition of stock after its sale can add business value beyond efficiently demonstrating compliance.

WHAT IS SERIALIZATION?

Essentially, serialization is the assigning of a predetermined coding type to each product item, conferring it with a unique identity that allows it to be effectively tracked at virtually any moment, and traced to its location at any stage of the production, logistics and / or marketing chain it is currently involved in, or had been involved in, at any point during its life cycle.

WHY SERIALIZE?

A number of reasons help explain what makes product serialization beneficial, especially for high-volume, easily counterfeited parenterals. Serialization at the unit level allows Grifols and its Grifols Partnership customers to:

[1] Take the concept of traceability one step further by uniquely identifying each product unit, thus moving away from the idea of tracing product units at a generic level, as is currently the case, where each product unit is only defined as part of the larger batch of products to which it belongs.
[2] Take full advantage of the increased level of traceability, in order to detect and prevent possible counterfeiting of our products.
[3] Comply with the regulations that are being put in place in an increasing number of countries, aimed at improving product traceability and detecting and preventing counterfeits.

HOW TO SERIALIZE

In order to serialize products, Track & Trace systems, tied to the company's IT infrastructure are used. A serialization and aggregation system implemented by Grifols and Grifols Partnership, allow parent-child relationships to be established between the different geographic locations of Grifols packaging facilities throughout the production process – primarily during / packaging processes (in Grifols' case, vials, single packs, multipacks, and pallets).

Grifols' serialization and aggregation systems and process make it possible to carry out track and trace operations at virtually any moment; not only in the supply process, but also during the logistic and marketing processes undergone by Grifols products, as well as those produced by Grifols Partnership for its customers. In addition to Grifols internal processes that include the relationship between the levels of serialization by product continent and the potential traceability throughout all aforementioned processes, the Grifols' system offers the following:

[1] **At the pallet level**: It is possible to track and trace operations at a logistics center level (wholesaler).
[2] **At the multipack level**: It is possible to track and trace operations at a distribution center level (wholesaler / retailer).
[3] **At the single pack level**: It is possible to track and trace operations at a hospital pharmacy level.
[4] **At the vial level**: It is possible to track and trace operations at the level of point of use of the drug.

TRACK & TRACE SYSTEM ELEMENTS

Track & Trace systems adhere to a five-level model, where each of the levels described below are interconnected and come together in a tree structure:

[1] **Level 1** defines the layout of and manages the serialization / aggregation system hardware that is incorporated into the machinery used in the production process.
[2] **Level 2** defines the layout of and manages the serialization / aggregation system at the production chain level (one level 2 manages one or more level 1s).
[3] **Level 3** defines the layout of and manages the serialization / aggregation system at the production plant level (one level 3 manages one or more level 2s).
[4] **Level 4** defines the layout of and manages the serialization / aggregation system

GRIFOLS:

Serialization Solutions

Our experience implementing a serialization solution for products manufactured by Grifols enables us to offer this service in projects undertaken for customers of Grifols Partnership. Grifols' Contract Manufacturing division is working hard in this regard in order to help customer's comply with the Drug Supply Chain Security Act (DSCSA) by November 17.

Requirements for the serialization of products to be distributed in the USA are stated in the DSCSA corresponding to Title II of the Public Law 113-54 published by the agency in November 2013 and include:

Product Identifier and Product Tracing

Both requirements have different timelines that are exposed hereinafter:

a. Product Identifier: A code composed by the Standard Numerical Identifier (unique ID for each product) + Batch number + Expiry. The implementation could be made by means of a datamatrix code or a linear barcode(depending on the product final packaging configuration). Data shall be codified as well as shown in a human readable form. Product identifier shall be implemented by November '17.

b. Product Tracing: This point refers to the fact that for all product transactions (understanding a transaction as the change in ownership of a product), the emitting entity shall provide the receiving entity with certain information. This information includes: transaction information, transaction history as well as transaction statement. Product Tracing shall be implemented in paper format (as minimum requirement) or electronic format by January '15 and in electronic format in November '17.

→ ABOUT THE AUTHOR

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Pere Vilanova studied Computer Engineering at university. He possesses Master's degrees in Quality Control Techniques, Quality Control Engineering and Management SAP Finance and Controlling. With almost 22 years working in different Grifols' companies (Diagnostic Grifols, Laboratorios Grifols, Grifols IT, Grifols Worldwide Operations in Ireland) and having experience on Production, Quality Control, Validations, Engineering, Track and trace systems and IT areas, Vilanova is currently heading the new IT Technology Development Area. He is mainly focused on RFID, 3D printing, industry 4.0, IoT, Big data and Manufacturing Execution System projects.

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at the Company level (one level 4 manages one or more level 3s).

[5] Level 5 defines the layout of and manages the serialization / aggregation system at an external level, chiefly to allow external access to data (drug agencies, logistics operators, hospitals, etc.). Generally speaking, a level 5 is fed information from a single level 4.

TRACK & TRACE SYSTEMS AT GRIFOLS

Grifols currently has two Track & Trace systems in place for the serialization and aggregation of hemoderivative products. These systems are:

[1] A single-product, single-country Track & Trace system that has been implemented in the [GBI] and [IG] production plants for the serialization and aggregation of albumin for the Chinese market, in compliance with the regulations imposed by the CFDA in 2013. This system covers levels 1, 2 and 3, as defined in the Track & Trace systems model, both at the single pack and multipack levels of the product.

[2] A multi-product and multi-country Track & Trace system, implemented initially in the GWWO Ireland production plant for the serialization and aggregation, at present, of albumin and flebogamma for markets of various countries, in compliance with the regulations established by each country respectively.

This system currently covers levels 1, 2 and 3, as defined in the Track & Trace systems model, both at the single pack and multipack levels of the product. At this time, the project is still live, and the implementation of levels 4 and 5, as defined in the Track & Trace systems model, is in progress both at the pallet level and, at a future date, at the vial level of the product.

Our experience implementing serialization solutions for Grifols broad range of sterile solutions, plasma and related parenteral products enables us to offer this service in projects undertaken for customers of Grifols Partnership. Grifols Contract Manufacturing division is working to help its customers in this regard in order to help them comply with the Drug Supply Chain Security Act (DSCSA) by November 2017. With well-integrated technologies and systems Grifols is ready to reap the continued benefits of Track & Trace, and ready to deliver similar capabilities to its contract manufacturing partners. P