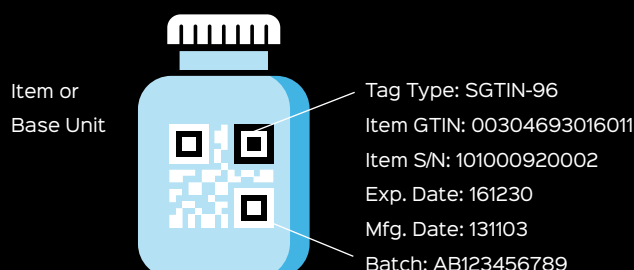# SERIALIZATION.

ARE YOU READY FOR SERIALIZATION AND TRACK AND TRACE REQUIREMENTS?

Due to counterfeiting, adulteration, theft, and diversion, governments and regulatory agencies have developed regulations to enhance patient safety and supply chain security. On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) made effective several additional requirements that impact labeling and data management for commercially distributed prescription human drug product in the US.

WHAT IS SERIALIZATION?

Serialization refers to the new requirements for application of unique identification code, a serial number or Electronic Product Code (EPC). The serial number should be applied to each unit in GS1 standard 2D DataMatrix and human-readable formats.

Item or Base Unit

Tag Type: SGTIN-96
Item GTIN: 00304693016011
Item S/N: 101000920002
Exp. Date: 161230
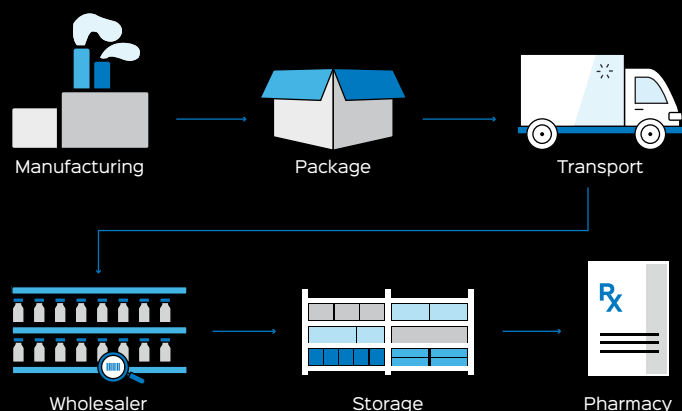Mfg. Date: 131103
Batch: AB123456789

WHAT IS TRACK AND TRACE?

Tracking, tracing, and authentication of serialized product through the supply chain means gathering and holding documentation of chain of ownership from manufacturing to dispensing in order to enable response to government requests for serial number verification in less than 24 hours. This metadata must be stored for six years.

WHAT ARE AGGREGATION/INFERENCE/ PACKAGING HIERARCHY?

Aggregation is the process of linking the serial number of each case to the individual serial numbers of units contained in that case, also referred to as the creation of the "parent/child relationship."

Manufacturing → Package → Transport

Wholesaler → Storage → Pharmacy

WHAT IS DRUG PEDIGREE/ePEDIGREE?

A statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of transaction and the names and addresses of parties involved. ePedigree refers to statements delivered electronically.

WHEN ARE THE KEY DEADLINES?

Jan 2015: Lot-level traceability requirement became effective.
Nov 2018: Unit level (serial #) requirement becomes effective; manufacturers must apply to bottle or carton and case/shipper. Although not required per DSCSA, most wholesale distributors are also requiring aggregation by this deadline.
Nov 2019: Wholesale distributors may not purchase or sell drug product without serialized product identifier.
Nov 2023: Full unit level traceability is required, including dispensers.

WHAT DOES THIS MEAN FOR YOU?

Commercially distributed human-use prescription drug products will require primary labeling with a larger print area for serial number barcoding. For existing products, this may require revisions to primary and secondary packaging to account for equipment and procedural changes related to the new complex serialized packaging process.

New software systems are needed for the generation, transfer, and retention of serial numbers in the accepted format. Connections to software systems at CMO/CPOs and trading partners will require setup, configuration, and testing. A connected supply chain enables traceability of the serial number of the lowest sellable unit from generation to dispensing within the 24 hour response timing required. Clearly defining responsibilities for data retention and response among all parties in the supply chain is critical.

THE ALCAMI ADVANTAGE.

Alcami has made significant investments to upgrade our packaging lines for full serialization and aggregation capability. Alcami has partnered with leading track and trace solution provider, TraceLink® to launch the enterprise level serial number management system, through TraceLink® Life Sciences Cloud, which will enable serial number generation and commissioning as well as data transfer with our clients and trading partners. Our serial number management system has flexibility to integrate with other solutions and supports various serial number provisioning models.

Committed to directing you to achieve consistent regulatory compliance, Alcami has successfully transitioned several clients into our serialization program and expect to continuously onboard additional clients. Connect with one of our experts to achieve the best outcome for your product at every level.

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