144 Must-Know Terms to Decipher Serialization

By early 2019, more than 75% of the world's prescription drug supply will be covered by track and trace laws. With so many markets adopting compliance regulations, it's very likely that your company sells product into one of them.

If your life sciences supply chain business is just beginning to delve into all the looming serialization requirements, you are likely encountering a lot of new—and potentially confusing—terminology. Serialization comes with a long list of abbreviated words, initialisms, and idiosyncratic definitions. You may have come across some in your day-to-day operations, but there will be many others you need to learn. What, for example, is the distinction between serialization and track and trace? And how does a batch differ from a bundle? As you get acclimated, use this glossary of more than 144 terms as a reference guide. The sooner you master the basic definitions, the faster you can move on to the larger—and time-sensitive—challenges of preparing for a serialized supply chain.

Download Glossary

#

3PL—Third-Party Logistics. A contracted company that provides distribution services of finished goods on behalf of another company. A 3PL never takes ownership of the product although the product is in its possession.

3PP—Third Party Printer. An organization that's contracted to print serial numbers

onto packaging containers.

A

ADR—Authorized Distributor of Record. A **wholesale distributor** that a **manufacturer** designates or authorizes to distribute its products.

Aggregation—The process of recording the serial number of a container along with the serial numbers of its contents; often referred to as a parent/child relationship, or a serialized container to content relationship.

Alphanumeric—Character set made up of digits and letters of the alphabet.

AS2—Applicability Statement 2. Protocol used to securely transmit data over the Internet. Preferred method for exchanging Electronic Data Interchange (EDI) transactions.

ASN—Advance Ship Notice, the common name for the EDI 856 transaction. A notification of pending deliveries, usually in an electronic format.

Asynchronous Transactions—Transactions that do not have to be completed before another transaction can be processed.

Authenticate—The practice of checking a unique identifier against a set of captured serialized data to determine its authenticity.

Auto ID—Methods for automatically capturing data encoded on items and containers, and entering that data directly into computer systems (i.e., without human involvement).

B

B2B—Business-to-Business. Interactions that support the transfer of standardized interchange files up to an enterprise's EDI system. B2B interactions are not

integrated with manufacturing, warehouse, or other backend business systems.

Batch—A group of products, usually associated by a manufacturing or packaging operation. Also referred to as a lot.

BoL—Bill of Lading. A document issued by a carrier which details a shipment of merchandise and gives title of that shipment to a specified party.

Bundle—A group of items held together, usually by shrink wrap. See also Inner Pack.

Bright Stock—An approach to labeling and packaging operations in which products are produced in large batches, stored in unlabeled containers, and then labeled just prior to shipment.

C

CAPA—Corrective And Preventive Action. Improvements to an organization's processes taken to eliminate quality failures.

Case—A container of product cartons which may or may not be bundled.

CBV—Core Business Vocabulary. Vocabulary elements agreed upon by trading partners who will exchange data. Example: For serialization, the GS1 standards organization publishes a CBV for EPCIS event data exchange (More at www.gs1.org/epcis).

Check Digit—Redundancy check used for error detection of identification numbers. Used in NDCs, DEA numbers, GTIN-14 identifiers, and SSCCs, for example.

CMO—Contract Manufacturing Organization. A company providing manufacturing, and sometimes packaging, services for one or more companies based on contracts or service agreements. Also referred to as a Contract Packaging Organization

(CPO) or Third Party Manufacturer (TPM).

Commission—Process of associating a unique identifier to a particular object (product, shipment, asset, or container).

Counterfeit—An imitation usually created with the intent of fraudulently passing it off as genuine, often to take advantage of the established worth of the imitated product. The word counterfeit frequently describes the forgeries of currency and documents, and the imitations of clothing, software, pharmaceuticals, jeans, watches, electronics, and company logos and brands. In the case of goods, it results in patent infringement or trademark infringement.

CPO—Contract Packaging Organization. A third-party organization that manufacturers will subcontract to package their product.

CSV—CSV Comma Separated Values. A common data exchange format stored in a tabular format. CSV files can be opened in spreadsheet programs.

CVM—The U.S. Center of Veterinary Medicine. The U.S. DSCSA regulates some products that are administered by veterinarians but can also be consumed by humans.

D

Data Carrier—A GS1 term for the different kinds of media, such as barcodes, that can hold GS1 identification keys and application identifiers.

DC—Distribution Center. A warehouse stocked with goods to be redistributed to retailers, wholesalers, or customers.

DEA number—A registration number assigned to an entity that is authorized by the U.S. Drug Enforcement Administration to manufacture, distribute, research, prescribe, or dispense a controlled substance. DEAs are used to track controlled substances and a valid DEA number consists of two letters, six numbers, and a

check digit. The first letter identifies the type of registrant, and the second letter is the first letter of the registrant's last name.

Decommission—The process of removing a unique identifier from a product or container so it is no longer tracked. Unlike the business process known as destroying, the item may still physically exist after decommissioning even though it no longer carries serialized identification.

Destroy—In instances where a product or container no longer exists, the process of removing a unique identifier from that item so it is no longer tracked.

Disaggregation—Disaggregation Removing products or containers from their associated parent container. The serial numbers of the contained items are no longer associated as children of the parent container.

Dispenser—A retail pharmacy, hospital pharmacy, group of chain pharmacies, or any other person authorized by law to dispense or administer prescription drugs. Under DSCSA, an entity is not considered a dispenser if it acts as a wholesale distributor or dispenses products only used for animals.

Disposition—The state of a serial number, such as commissioned or decommissioned.

Double Byte Character Set—Character encoding that contains a large number of unique characters or symbols used to express languages such as Japanese, Korean, and Chinese.

Downstream—The direction in which product flows in a supply chain. Generally speaking, pharmaceutical products flow, and transactions occur, through the supply chain from manufacturers, to repackagers, to wholesale distributors, to dispensers.

DQSA—The Drug Quality and Security Act. U.S. Federal legislation passed in

November 2013.

DSCSA—The **Drug Supply Chain Security Act**, which is Title II of DQSA. **DSCSA mandates** a full supply chain traceability system from pharmaceutical manufacturer to pharmacy dispenser for prescription drugs being distributed in the United States. The law was signed by President Obama in November 2013, providing a national standard for drug security and replacing the patchwork of state-level Pedigree regulations that were in place.

DUNS (D-U-N-S) Number—A unique nine-digit identifier assigned and maintained by Dun and Bradstreet (D&B) to identify business entities on a location-specific basis.

DUNS+4—A DUNS number plus a 4-digit extension (13 digits total) created by entities that have been assigned DUNS numbers, if they need more than one bank/Electronic Funds Transfer (EFT) account for a location. Dun & Bradstreet does not create or maintain the +4 number.

E

Each—An individual saleable unit entering the supply chain, such as a finished goods bottle or unit carton.

ECC—Error Correction Coding. A code applied to transferred data for error control. Provides redundancy and allows the receiver to recover the original data.

EDI—Electronic Data Interchange.The electronic transfer of data between computer systems in a standardized message format.

Encoding—A state for serial numbers. If an organization pre-prints labels for serial numbers after they are provisioned, the serial numbers enter the encoding state. Once the labels are affixed to the products, the serial numbers enter the commissioned state.

EPC—Electronic Product Code. A unique number that identifies a specific item in the supply chain. Also known as a serial number.

EPCglobal—The organization developing standards for the Electronic Product Code (EPC), and for RFID systems to store and manage EPCs. EPC Global is sponsored by GS1.

EPCIS—Electronic Product Code Information Services. A GS1 EPCglobal standard designed to enable EPC-related data-sharing within and across enterprises. This data-sharing is aimed at enabling participants in the EPCglobal Network to obtain a common view of the disposition of EPC-bearing objects within a business context. (More at www.gs1.org/epcis).

ERP—An Enterprise Resource Planning system. Business process management software used to manage and automate back-office operations.

European Hub—A cloud-based gateway for EU compliance reporting. Provides interoperability between different national systems in the EU, and managing product status (such as decommissioning and recalls) and exceptions throughout the life cycle of a product. The hub doesn't store serialization data like a repository – instead it acts as a single point of entry.

Event Repository—A computer system designed to store serial number information, and events relating to serialized products.

Exclusive Distributor—A wholesale distributor that purchases directly from a manufacturer and is the sole distributor of that manufacturer's product.

Expiry—Date of expiration for an item, or the last day the item should be used.

Extension Digit—A one-digit segment used to extend the serial reference segment of an SSCC identifier.

External Product Identifier—A standards-based product code, such as a Global

Trade Item Number (GTIN), or a market-specific product code used to identify the product in the external supply chain. This is specifically not a manufacturer SKU, which is not regulated or standardized.

F

Filter Value—A one-digit value that companies specify in serial number formats. Typically, companies specify filter values as units of measure in order to convert to different formats.

FMD—The Falsified Medicines Directive. A pan-European directive, also referred to as EU FMD, intended to protect patients from counterfeit medicines in the legal distribution chain. The European Medicines Verification System (EMVS) was developed to implement the FMD.

Functional Specification(FS)—In systems engineering and software development, a functional specification (also, functional spec, specs, functional specifications document [FSD]) is the documentation that describes the requested behavior of an engineering system. The documentation typically describes what is needed by the system user, as well as requested properties of inputs and outputs (e.g., of the software system).

G

GCP—Global Company Prefix. A globally unique code that is used to represent a location in identifiers. See also GS1 Company Prefix.

GLN—Global Location Number. A unique 13-digit number containing a GS1 company prefix, a location reference, and a check digit, used to uniquely identify a physical location or legal entity in the supply chain. The GLN makes possible the unique and unambiguous identification of those locations and entities.

Global Identifier—A unique reference number used to identify a legal entity such

as a company or location, to support the secure exchange of business information on the Internet.

Grandfathering—A provision in which some pre-existing situations are not subject to a new rule or regulations. For example, under FMD, products that are packed and released for sale before the law takes effect may be distributed and sold until their expiry date, if they are not repackaged or relabeled. Under the DSCSA, grandfathering guidance from the FDA is pending.

GS1—A leading global organization dedicated to the design and implementation of global standards and solutions, to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world. (More at www.gs1.com).

GS1-128—A linear barcode, formerly referred to as a Code-128 barcode. Usage is granted to organization members of GS1.

GS1 Company Prefix—A globally unique identifier for a company, assigned and administered by GS1 Global. The GS1 Company Prefix is 4 to 12 digits, and is a component of GLN, GTIN, and SSCC identifiers.

GS1 Datamatrix—A two-dimensional matrix barcode consisting of black and white “cells” or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data. Usage is granted to organization members of GS1.

GTIN—Global Trade Item Number. An identifier for trade items, developed by GS1. Such identifiers are used to look up product information in a database, often by inputting the number via a barcode scanner pointed at an actual product. The uniqueness and universality of the identifier is useful in establishing which product in one database corresponds to which product in another database, especially across organizational boundaries. Usage is granted to organization members of

GS1.

GxP—Good Practice. A general term, usually referring to quality and regulations. For example, GMP is “Good Manufacturing Practice” and GCP is “Good Clinical Practice.”

H

HDA—(formerly HDMA) Healthcare Distribution Alliance (formerly the Healthcare Distribution Management Association). The national association in the U.S. representing primary, full-service healthcare distributors. HDA member companies deliver more than nine million prescription medicines and healthcare products to more than 165,000 settings including chain and community pharmacies, hospitals, nursing homes, physician offices, and clinics in every state and territory.

Header—(for Human Readable Interpretation) Headers comprise the prefixes used in Human Readable Interpretation of variable data. Common headers include GS1 Application Identifiers (AIs) or GS1 recommended field labels.

HIN—The Health Industry Number. A nine-character alphanumeric unique identifier that is assigned to every facility, delivery location, and business activity in the healthcare supply chain. The first seven positions comprise the “base HIN,” which identifies a healthcare entity at a particular location.

HRI—Human Readable Interpretation. Characters, such as letters and numbers, which can be read by people and are encoded in data carriers. HRI is a one-to-one illustration of the encoded data.

I

Illegitimate Product—Defined by the FDA as a product for which credible evidence shows that it (a) is counterfeit, diverted, or stolen, (b) is intentionally adulterated such that the product would result in serious adverse health

consequences or death to humans, (c) is the subject of a fraudulent transaction, or (d) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Inference—The technique of assuming the serial numbers within a sealed container based on previous observation, and not by directly reading each serial number. Inference is accomplished using data systems or documents (see Pedigree) and is controlled through validated procedures.

Inner Pack—A group of items (see Bundle) held together, usually by shrink wrap.

Inspection—The process of reviewing an item, either manually or using automated systems.

Internal Material Number—A number assigned to a product for internal use and not for identifying the product externally.

Interoperability—The ability of technology systems and software to communicate, exchange data and/or information, and make use of the information that’s been exchanged.

IQ—Installation Qualification. Demonstrates that a process or equipment meets all specifications, is installed correctly, and that all the required components and documentation needed for continued operation are installed and in place.

Item—The product secondary package level, typically a carton. Also referred to as the smallest saleable unit.

L

L1 – L5—The 5 levels of serialization and information management: L5 – Network-level serialization system, L4 – Enterprise serialization system, L3 – Site-level serialization, L2 – Packaging line software, L1 – Device.

LDAP—Lightweight Directory Access Protocol. An industry standard protocol for accessing and maintaining distributed directory information services.

LMS—Line Management System. A system that manages a production line and interfaces with a company's Enterprise Resource Planning (ERP) system.

Logistic Labeling—Comprises the data and process of printing labels for use on all containers above the secondary packaging level. For example, shipper and pallet labels.

M

MAH—Marketing Authorization Holder. The license holder (brand owner) of a pharmaceutical product. Manufacturer An entity or organization responsible for packaging of the product.

Master Data—Data representing a company's details, global identifiers, products, and trading partners. Particular types of data are required for serialization and global compliance reporting.

MES—Manufacturing Execution System. A control system for managing and monitoring work-in-process on a factory floor.

N

National System—An information system set up and governed by national stakeholders to ensure a medicine's authenticity by verifying its safety features, to prevent falsified products from entering the supply chain.

NDC—National Drug Code. A unique 10-digit product identifier for human drugs in the U.S. Represents the labeler or vendor, the product, and the package size. Some government agencies have adopted 11-digit NDCs by padding the identifier with leading zeros.

NEDL—National Essential Drug List. The drugs that satisfy the healthcare needs of the majority of the population.

NTIN—National Trade Item Number. A product identifier that adopts the structure of a GTIN and is assigned by a third-party national agency. An NTIN contains a country-specific drug registration number.

O

OEE—Overall Equipment Effectiveness. Evaluation of the effectiveness of a manufacturing operation.

OQ—Operational Qualification. Demonstrates that all facets of a process or equipment are operating correctly.

P

Pack Marking—Comprises the data and process for printing on primary and secondary product packaging.

Packaging and Labeling—Generally, related to the physical material, artwork, and printing that's used with all levels of product and logistics containers.

Pallet—A flat transport structure (sometimes called a skid) that supports goods in a stable fashion while being lifted by a forklift, pallet jack, front loader, or other jacking device. A pallet is the structural foundation of a unit load, which allows handling and storage efficiencies. Goods or shipping containers are often placed on a pallet secured with strapping, stretch wrap, or shrink wrap, and then shipped.

Parallel Importer—An organization that buys a product on the open market with the intention to repackage or relabel, and then distributes it outside the network that's set up by the manufacturer or that manufacturer's authorized distributor.

Pedigree—A certified record that contains information about each distribution of a

prescription drug. It records the sale of an item by a manufacturer, any acquisitions and sales by wholesalers or repackagers, and final sale to a pharmacy or other entity administering or dispensing the drug. The process generally begins with the serialization of a product, and then continues through the supply chain as the product is received by each trading partner.

PEDL—Provincial Essential Drug List. The drugs that satisfy the healthcare needs of the majority of the population of a nation or province. See also NEDL.

Picking—The process of collecting articles in a warehouse to fulfill a customer order.

PQ—Performance Qualification. The documented evidence that a system, equipment, or process is capable of consistently producing a safe product of high quality. Performance Qualification protocol describes the procedures that verify the specific capabilities of a process equipment/system through the use of simulation material and/or actual product.

Primary Package—Primary containment system in which the product is sterilized (excluding shelf cartons and shipping containers) that protects the contents to the intended level over a specific period of time.

Product Code—A unique identifier assigned to each finished manufactured product that is ready to be marketed or sold. Also known as Universal Product Code, a common barcode used to identify packaged products.

R

Recall—The removal of a drug product from the market. In the U.S., recalls fall under three classifications: Class I is for those products that can probably lead to adverse health effects or death; Class II is for drugs that can cause temporary or reversible health effects; and, Class III relates to instances where the drug is not likely to cause adverse health effects.

RFID—Radio-Frequency Identification. The use of an object, typically referred to as an RFID tag, applied to or incorporated into a product, animal, or person, for the purpose of identification and tracking using radio waves.

S

Safety Features—Elements, such as anti-tampering devices and barcodes carrying product and pack data, that are incorporated into a medicine product's packaging and identification to facilitate verification. Under FMD, for instance, safety features contain a) a unique identifier encoded in a 2D barcode, and b) anti-tampering technologies.

SAN—Storage Area Network. A network that provides access to consolidated, block-level data storage.

SCAC—Standard Carrier Alpha Code. Code used to identify transportation companies.

SDB—Serialization database. A level 4 serialization system.

Segment—Part of a market or industry. The pharmaceutical supply chain includes segments such as manufacturer, wholesaler, dispenser, Contract Manufacturing Organization (CMO), Third-Party Logistics (3PL) companies, and repackagers (also known as Third-Party Packagers or 3PPs).

Serial Number—Typically a portion or component of a Unique Identifier (UID) which provides uniqueness. Also known as a serial reference.

sFTP—Secure File Transfer Protocol. A network protocol that provides file access, transfer, and management over a secure channel.

SGLN—Serialized Global Location Number. A unique identifier to a physical location, such as a specific building or bin within a warehouse. The GLN is a GS1 format; the SGLN is an EPC format and is represented in Uniform Resource

Identifier format, for example: urn:epc:id:sgln:0030001.12345.400.

sGTIN—Serialized Global Trading Item Number. The combination of a Global Trade Identification Number and a serial number which uniquely identify an item.

Site Server—A computer system located in a specific locale responsible for a location-specific function. In traceability systems, site servers usually refer to local servers which allocate serial numbers to packaging control systems and/or manage serial number information before it is transmitted to an enterprise traceability event repository.

SKU—Stock Keeping Unit. Specifies a distinct type of item for sale. SKUs are not regulated or standardized and thus are not used for serialization.

Smallest Saleable Unit—Each individual package of drug product, also known as the primary package level. The sealed homogenous case in which smallest saleable units are packaged is the secondary package level.

sNDC—Serialized National Drug Code. The accepted format of unique identifier (UID) as defined by the U.S. FDA for serialization of U.S. marketed products. The sNDC is comprised of the NDC plus a serial number.

SNI—Standardized Numerical Identifier. A standard identifier affixed to a prescription drug package.

SOAP—Simple Object Access Protocol. A messaging protocol for exchanging structured (XML) information in the implementation of web services.

SOR—System of Record. An information storage system that is the authoritative data source for a given data element or piece of information.

SSCC—Serial Shipping Container Code. A GS1 standard used in logistic encoding and communications. The SSCC ensures that logistic units are identified with a number that is unique worldwide.

SSO—Single Sign On. A session and user authentication service that allows software system users to log in with a single username and password, to access connected systems without using different usernames and passwords.

Synchronous Processing—Type of processing that provides an immediate response to a query. SOAP and REST web services provide synchronous processing.

T

T3—Under DSCSA, the combination of Transaction Information (TI), Transaction History (TH), and the Transaction Statement (TS) for a drug product as it moves through the drug supply chain.

TH—Transaction History. A record of transaction information for each change of ownership within the supply chain, starting with the manufacturer. THs Transaction Histories. Documentation for transaction exchanges of multiple products, including (for each product) all three transaction documentation components: TI, TH, and TS. See also Transaction, TH.

TI—Transaction Information. A comprehensive set of details about each product included in a transaction, including product name, National Drug Code (NDC) number, strength and dosage form, size and number of containers, lot number, date of transaction, and the names of the companies involved in the transaction. TPM Third-Party Manufacturer. A company contracted to manufacture drug product for a brand owner. Also referred to as a contract manufacturer, Contract Manufacturing Organization (CMO), or Third-Party Packager (3PP).

TPO—Third-Party Organization. Term used to refer to any TPM, 3PL, CMO, or other externally contracted organization.

Transaction—As defined by DSCSA, the transfer of product where a change of ownership occurs. Exemptions: intercompany distributions, distribution among

hospitals under common control, public health emergencies, dispensed pursuant to a prescription, product sample distribution, blood and blood components for transfusion, minimal quantities by a licensed pharmacy to a licensed practitioner, charitable organizations, distributions pursuant to a merger or sale, certain combination products, certain medical kits, certain IV products, medical gas distribution, approved animal drugs.

TS—Transaction Statement. A statement confirming that trading partners are authorized by law to transfer ownership of product, have received transaction documentation, have systems in place to comply with verification requirements, and did not knowingly ship suspect product or provide false information.

Track and Trace—The process of tracking drugs through the supply chain using serialization data. Track and trace systems begin with serialization but generally include additional components such as product tracing or tracking, verification, and/or reporting.

U

UID—Unique Identifier. A string of numbers and characters that is unique within a given system. Examples include GS1 GTIN and GS1 SSCC identifiers.

UPC—Uniform Product Code. The U.S. standard article number. A form of GTIN data carrier or barcode.

Upstream—The opposite direction that product flows in a supply chain; moving back up the supply chain. Generally speaking, the pharmaceutical product flows, and transactions occur, through the supply chain from manufacturers, to repackagers, to wholesaler distributors, to dispensers.

User—An entity, individual, or organization responsible for making use of product, process, or systems.

V

Validation—Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

VAN—Value Added Network. A hosted service offering that acts as an intermediary between business partners sharing standards-based or proprietary data, via shared business processes.

VAWD—Verified-Accredited Wholesale Distributors. An accreditation for pharmaceutical wholesale distribution facilities. Wholesale distributors that achieve accreditation are in compliance with state and federal laws, and the U.S. National Association of Boards of Pharmacy's VAWD criteria.

Virtual(Manufacturer)—A company that outsources services to a manufacturer/CMO.

W

Wholesale Distributor—A company that distributes drugs to an entity other than a consumer or patient.

WMS—Warehouse Management System. A software application that supports the day-to-day operations within a warehouse. A WMS enables centralized management of tasks such as tracking inventory levels and stock locations.

WSDL—Web Service Definition Language. An XML-based interface used to describe the functionality of a web service.

X

XSD—XML Schema Definition. Describes the structure of an XML document

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